



HeartWare[®] Ventricular Assist System

Instructions for Use

Caution: Federal law restricts this device to sale by or on the order of a physician.

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FOREWORD

The HeartWare® Ventricular Assist System is indicated for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. Clinical users include physicians, registered nurses, perfusionists and biomedical engineers. Implant of the device must be performed by a qualified cardiac surgeon trained by HeartWare-authorized personnel. Clinical users of the HeartWare® System should attend HeartWare clinical operator training, should have a working knowledge of the principles of left ventricular assist devices (LVADs), and should be aware of the physical and psychological needs of patients undergoing LVAD support. Patients and caregivers should complete a user training program and demonstrate their ability to use the system. Clinicians should read the entire Instructions for Use before system operation. This manual may serve as a reference for detailed information including specific information on device function, system setup, implant and maintenance. This manual is not intended to replace comprehensive educational programs or to supersede acquired knowledge or proper medical judgment.

WARNING! Carefully read this entire manual prior to implanting or operating the device. Improper operation of the system and potential harm to the patient and to the user could result.

1.0 INTRODUCTION

STERILE: All HeartWare components used at implant including surgical tools are provided sterile.

The HeartWare® Ventricular Assist System (HeartWare® System) is designed to assist a weakened, poorly functioning left ventricle. The HeartWare® System utilizes a centrifugal blood pump, the HVAD® Pump (the “pump”), which is implanted in the pericardial space with left ventricular apex to ascending aortic cannulation for left ventricular support (Figure 1). The inflow conduit, which is partially sintered, is integrated with the pump and a 10mm gel impregnated outflow graft with a strain relief is attached to the pump. A percutaneous driveline connects the pump to an external controller. The controller, powered by two batteries or by one battery and electricity from the wall or car outlet, regulates pump function and monitors the system. The monitor is used to display system performance and to change controller operating parameters. A battery charger is also included.

All components of the HeartWare® System are designed to be used only in conjunction with each other. They are neither compatible nor intended to be used with other manufacturer’s devices.

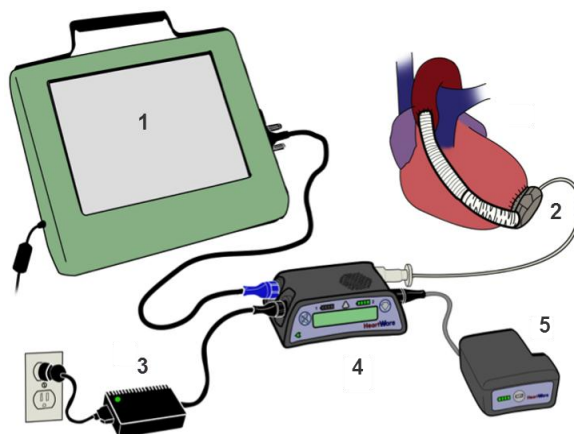


Figure 1: HeartWare® Ventricular Assist System

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|---------------|---------------|
| 1. Monitor | 4. Controller |
| 2. HVAD® Pump | 5. Battery |
| 3. AC Adapter | |

2.0 INDICATIONS FOR USE

The HeartWare® Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The HeartWare® System is designed for in-hospital and out-of-hospital settings, including transportation via fixed wing aircraft or helicopter.

3.0 CONTRAINDICATIONS

The HeartWare® System is contraindicated in patients who cannot tolerate anticoagulation therapy.

WARNING! Serious and life threatening adverse events, including stroke, have been associated with use of this device. A user must fully consider the risks of this device with that of other treatment modalities before deciding to proceed with device implantation. Please see Section 6.4 for a summary of the stroke data.

WARNING! Do not use the HeartWare System in pregnant women. Any woman receiving a HeartWare System who is of childbearing age and sexually active should use a reliable method of birth control. Use of anticoagulants during pregnancy has been associated with birth defects and bleeding.

4.0 WARNINGS

1. **WARNING!** The Instructions for Use (IFU) is intended to be used by physicians, nurses, and other clinical professionals. Setup and operation of this device should only be undertaken by personnel who have completed a HeartWare product training program. A thorough understanding of technical principles, clinical applications and risks associated with the HeartWare® System is required before using this product. Failure to understand these principles, applications and risks may result in improper operation of the system and potential harm to the patient or to the user.
2. **WARNING!** Carefully read this entire manual prior to implanting or operating the device. Improper operation of the system and potential harm to the patient and to the user could result.
3. **WARNING!** Serious and life threatening adverse events, including stroke, have been associated with use of this device. A user must fully consider the risks of this device with that of other treatment modalities before deciding to proceed with device implantation. Please see Section 6.4 for a summary of the stroke data. To mitigate the risk of stroke, please adhere to the following patient management guidelines:
 - Maintain MAP at <85 mm Hg as tolerated. The HVAD® Pump is sensitive to both preload and afterload.
 - Ramp speed and flows more slowly during the first few weeks (e.g. 30 days) post-implant to avoid excessive hemodynamic forces that may damage fragile blood vessels that have undergone remodeling secondary to the lower pressures and reduced flow associated with medically-treated heart failure. There is no apparent need to exceed a cardiac index of 2.6 L/min/m² until patients have fully recovered from the implant surgery and physical

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- performance improves. A cardiac index of 2.6 L/min/m² is the lower limit of normal for a healthy adult.
- Maintain anticoagulation within the recommended INR range of 2.0-3.0.
 - Check for ASA resistance with a reliable test (e.g. VerifyNow®) and adjust ASA mono-therapy accordingly or consider combination therapy such as ASA 81 mg plus Aggrenox® (ASA plus extended –release dipyridamole) or daily ASA 81 mg plus Plavix 75 mg. In general, mono-therapy with ASA is not encouraged in the absence of testing for resistance.
4. **WARNING!** Do not use the HeartWare System in pregnant women. Any woman receiving a HeartWare System who is of childbearing age and sexually active should use a reliable method of birth control. Use of anticoagulants during pregnancy has been associated with birth defects and bleeding.
 5. **WARNING!** NEVER disconnect both power sources (batteries and AC or DC adapter) at the same time since this will stop the pump. At least one power source must be connected at all times.
 6. **WARNING!** DO NOT rely only on flow estimation to assess cardiac output. An average estimated flow on the monitor or controller display of less than 2 L/min, or greater than 10 L/min may indicate an electrical fault, incorrect hematocrit entry or an occlusion due to thrombus or other materials (e.g. tissue fragments) in the device. Inaccurate assessment of HVAD® Pump flow may lead to less than optimal treatment.
 7. **WARNING!** ALWAYS investigate, and if possible, correct the cause of any alarm. Silencing an alarm does not resolve the alarm condition.
 8. **WARNING!** DO NOT grasp the driveline cable as this may damage the driveline. To remove the driveline from the controller, first pull back the driveline cover then grasp and pull the driveline connector.
 9. **WARNING!** DO NOT disconnect the driveline from the controller or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.
 10. **WARNING!** DO NOT operate the controller in temperatures less than -20°C (-4°F) or greater than 50°C (122°F) or the controller may fail.
 11. **WARNING!** DO NOT attach the alarm adapter to a controller connected to the running pump. The alarm adapter silences the “No Power” alarm and should only be attached to a controller that has failed or malfunctioned and is no longer connected to a pump.
 12. **WARNING!** ALWAYS keep a spare controller and fully charged spare batteries available at all times in case of an emergency.
 13. **WARNING!** DO NOT plug the AC adapter into an electrical outlet which is not properly grounded or you may receive a serious electrical shock.
 14. **WARNING!** ALWAYS check the controller display for any information regarding an alarm when using loud machinery or in the vicinity of loud noises as the alarms may not be audible.
 15. **WARNING!** ALWAYS replace a controller with a blank display or no audible alarms. This condition is predictive of a controller failure.
 16. **WARNING!** ALWAYS switch to the backup controller if there is a “Controller Failed” alarm since the HVAD® Pump may not be running.
 17. **WARNING!** The HVAD® Pump may cause interference with AICDs. If electromagnetic interference occurs, it may lead to inappropriate shocks, arrhythmia and possibly death. The occurrence of electromagnetic interference with AICD sensing may require adjustment of lead sensitivity, proximal placement of new leads or replacement of an existing sensing lead.
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18. **WARNING!** Keep both power supplies connected to the controller after setting up the primary controller to minimize the risk of air embolus during implant. Disconnecting and then reconnecting both power supplies will result in the controller starting the pump as soon as the driveline is connected.
19. **WARNING!** DO NOT use if package is damaged or opened. Sterile components are intended for single use only. DO NOT re-sterilize or re-use as this will increase the risk of infection.
20. **WARNING!** ALWAYS check for an audible click when connecting the driveline to the controller or driveline extension cable. Failure to ensure a secure connection may cause an electrical fault.
21. **WARNING!** NEVER turn on the HVAD® Pump in air as this may damage the pump. DO NOT use an HVAD® Pump that was turned on without total submersion in fluid during the pre-implant test and prior to implantation: The HVAD® Pump must be completely submerged in fluid before being turned on.
22. **WARNING!** DO NOT implant gel impregnated vascular prostheses in patients who exhibit sensitivity to polyester or materials of bovine origin, as severe reactions may occur.
23. **WARNING!** DO NOT allow the Gelweave prostheses non-sterile foil pouch or outer tray to be introduced to the sterile field or the sterile field will be contaminated. Only the innermost tray is sterile.
24. **WARNING!** DO NOT preclot the outflow graft. Preclotting may disrupt the gel matrix, resulting in bleeding. Gelweave prostheses are sealed grafts and must not be preclotted.
25. **WARNING!** DO NOT implant the Gelweave prostheses more than one month after removal from the foil pouch. This may disrupt the gel matrix, resulting in bleeding.
26. **WARNING!** DO NOT allow anyone but a surgeon, physician's assistant or surgical assistant trained in the procedure to attach the outflow graft to the pump, as a loose graft connection may lead to bleeding and/or an air embolus.
27. **WARNING!** ALWAYS rotate the strain relief so that the clamp screw is located on the inner side of the outflow conduit to avoid tissue irritation or damage.
28. **WARNING!** DO NOT use excessive force when tightening the clamp screw because this could damage the graft clamp or graft clamp screw and a loose connection may result in bleeding and/or an air embolus. Replace components if required.
29. **WARNING!** DO NOT over-loosen the sewing ring's screw or it may fall off the sewing ring and be lost in the sterile field.
30. **WARNING!** DO NOT cut the outflow graft too short or too long, or it may kink. Prior to chest closure, ensure that the graft is not kinked or compressed. A kinked or compressed outflow graft may lead to reduced flow and/or thrombus formation.
31. **WARNING!** DO NOT immerse the Gelweave grafts in saline for longer than 5 minutes. Longer periods of soaking in saline may disrupt the gel matrix, resulting in bleeding.
32. **WARNING!** ALWAYS position the driveline exit site so that the tunneler does not contact any vital organs or structures.
33. **WARNING!** DO NOT grasp the driveline and pull as this may damage the driveline. To remove the driveline cap from the driveline, unscrew the outer sleeve, then pull back on the grooved part of the connector.

34. **WARNING!** ALWAYS remove all air from the HVAD® Pump and its conduits to reduce risk of air embolus.
 35. **WARNING!** DO NOT de-air the HVAD® Pump when there is inadequate blood volume in the HVAD® Pump or leaks in the inflow/outflow connections, as air may enter the HVAD® Pump and outflow graft resulting in a delay in de-airing and possible air embolism.
 36. **WARNING!** DO NOT allow patients to shower until they have received permission from their clinician to do so. Patients who shower must use the HeartWare® Shower Bag.
 37. **WARNING!** DO NOT allow hearing impaired patients to shower unless their caregiver is close by to hear alarms.
 38. **WARNING!** DO NOT plug the controller into an AC wall outlet during showers; to eliminate the possibility of a severe electrical shock, it should be connected to two batteries.
 39. **WARNING!** DO NOT allow patients to take a bath or swim, as this may damage HeartWare® System components and/or result in driveline exit site infection.
 40. **WARNING!** DO NOT submerge HeartWare® System components in water or other fluid as this may damage them. If this happens, contact HeartWare.
 41. **WARNING!** DO NOT allow water or other fluids to enter the controller, power adapters, batteries, battery charger or connectors, as this may damage HeartWare® System components. If this happens, contact HeartWare.
 42. **WARNING!** AVOID areas with high magnetic forces such as theft detection devices or airport security systems, as this may affect HeartWare® System operation.
 43. **WARNING!** Keep mobile phones at least 20 inches (50 centimeters) away from the controller, as mobile phones may interfere with controller operation.
 44. **WARNING!** DO NOT let the patient have a magnetic resonance imaging (MRI) procedure while implanted with the HVAD® Pump. Doing so could cause harm to the patient or could cause the pump to stop.
 45. **WARNING!** DO NOT apply high power electrical treatment (e.g. application of diathermy) directly to the patient, as this may affect HeartWare® System operation.
 46. **WARNING!** AVOID therapeutic levels of ultrasound energy, as the device may inadvertently concentrate the ultrasound field and cause harm.
 47. **WARNING!** AVOID therapeutic ionizing radiation since it may damage the device. This damage may not be immediately detectable.
 48. **WARNING!** DO NOT use any components other than those supplied by HeartWare with the HeartWare® System, as this may affect HeartWare® System operation.
 49. **WARNING!** DO NOT drop the controller or other equipment. Dropping the controller could cause sudden stoppage of the pump. Dropped equipment should be reported to HeartWare and inspected.
 50. **WARNING!** Damaged equipment should be reported to HeartWare and inspected.
 51. **WARNING!** NEVER clean the battery charger with the power on, as this may lead to an electrical shock.
 52. **WARNING!** NEVER clean the monitor with the power on, as this may lead to an electrical shock. DO NOT use alcohol or detergent on the monitor display. Gently wipe the display with a soft, lint free cloth.
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53. **WARNING!** DO NOT disconnect the driveline or power sources from the controller while cleaning it or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.

5.0 PRECAUTIONS

1. **CAUTION:** Safety and effectiveness in persons less than 18 years of age and in persons with a BSA of less than 1.5 m² have not been established.
2. **CAUTION:** The HeartWare® Ventricular Assist System has had limited use in patients with artificial mitral or aortic valves and therefore the risks are currently unknown. Caution should be used in selecting patients with artificial mitral or aortic valves for HeartWare® System therapy.
3. **CAUTION:** ONLY use HeartWare® Controllers on one patient to avoid risks associated with an inadvertent mismatch of controller pump speed settings.
4. **CAUTION:** Manual changes to the speed will immediately disable the ventricular suction detection alarm. An “Sx Off” will be displayed on the monitor screen below the “Fixed” mode display. The ventricular suction detection alarm will have to be re-activated.
5. **CAUTION:** DO NOT enable the ventricular suction detection alarm while the patient is in a suction condition. To optimize operation of the suction detection the patient should be hemodynamically stable prior to enabling the ventricular suction detection alarm.
6. **CAUTION:** ALWAYS fully charge the monitor’s internal battery prior to patient use.
7. **CAUTION:** DO NOT allow patients to touch the monitor, as this may lead to the entering of unwanted HeartWare® System parameters.
8. **CAUTION:** DO NOT use the “Set Defaults” button on the monitor when a controller is connected to a patient. Pressing it will erase all patient VAD parameter information from the controller.
9. **CAUTION:** ALWAYS recharge fully depleted batteries within 24 hours to avoid permanent battery damage.
10. **CAUTION:** DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.
11. **CAUTION:** ALWAYS confirm that the power cables are properly locked on the controller by gently pulling the cable near the controller power connector or the power cables may come loose and result in an alarm or the pump stopping.
12. **CAUTION:** DO NOT expose batteries to temperatures outside the storage and operational ranges or they may provide less support than usual. To preserve battery life, batteries should be stored at room temperature.

Battery operating and storage temperatures:

- a. Operating: discharge (normal use with the HeartWare® System) and charge (while on battery charger): 0°C to 45°C (+32°F to 113°F). Operation at temperatures below 0°C will **temporarily** reduce battery capacity but the battery will operate.
 - b. Storage: -20°C to 25°C (-4°F to 77°F). Long term storage outside of this range may **permanently** reduce the battery capacity. Best condition for storage is at room temperature.
13. **CAUTION:** ALWAYS keep batteries away from children. Children may be harmed by damaged batteries or components.

14. **CAUTION:** DO NOT disassemble, crush, or puncture a battery.
15. **CAUTION:** DO NOT use a damaged battery. Battery function is unknown if the battery is damaged.
16. **CAUTION:** DO NOT short circuit the external contacts on a battery since this may result in battery damage.
17. **CAUTION:** DO NOT touch the fluid if a battery pack is leaking fluid. Dispose of a leaking battery pack. In case of eye contact with fluid, DO NOT rub eyes. Immediately flush eyes thoroughly with water for at least 15 minutes, lifting upper and lower lids, until no evidence of the fluid remains. Seek medical attention.
18. **CAUTION:** DO NOT expose batteries to excessive shock or vibration since this may affect battery operation.
19. **CAUTION:** DO NOT dispose of a battery in fire or water. Dispose of batteries according to federal, state, and local regulations.
20. **CAUTION:** ONLY use the HeartWare® Battery Charger to charge HeartWare® Batteries. Other battery chargers will not charge the batteries and may damage them.
21. **CAUTION:** ALWAYS wait until the “Ready” light turns on to disconnect the battery from the battery charger. If this is not followed over consecutive charging cycles, the Battery Capacity Display will not function properly and may convey misleading battery capacity.
22. **CAUTION:** DO NOT use HeartWare equipment in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
23. **CAUTION:** A backup controller should always be available and programmed identically to the primary controller.
24. **CAUTION:** DO NOT exert excessive tension or force on the Gelweave prostheses as it will damage the polyester fibers and the gelatin impregnation, which may result in bleeding.
25. **CAUTION:** ALWAYS ensure the inflow cannula position is pointed toward the mitral valve and parallel to the interventricular septum to optimize HVAD® Pump operation.
26. **CAUTION:** ALWAYS position the sewing ring to permit access to its screw after cannulation.
27. **CAUTION:** ALWAYS use round body taper point needles when implanting Gelweave prostheses to minimize fiber damage. A kinked or compressed outflow graft may lead to reduced flow and/or thrombus formation.
28. **CAUTION:** The driveline connector is made of nickel-coated brass which may cause a rash in patients with a nickel allergy.
29. **CAUTION:** ALWAYS be aware of the position of the driveline to avoid damage by surgical instruments and needles during HVAD® Pump implantation and/or re-operation.
30. **CAUTION:** ALWAYS use the smallest possible needle for de-airing; 19-gauge is normally sufficient. Hypodermic needles have a cutting point which may result in blood leakage and may require repair by suturing.
31. **CAUTION:** DO NOT rely on HVAD® Pump flow estimation during the de-airing procedure. Flow estimation may not be accurate.
32. **CAUTION:** Chest compressions may pose a risk due to pump location and position of the outflow graft on the aorta - use clinical judgment. If chest compressions have been administered, confirm function and positioning of HVAD® Pump.

33. **CAUTION:** ALWAYS examine the driveline for evidence of tears, punctures or breakdown of any of the material during exit site dressing changes. Driveline damage may affect HeartWare® System performance.
34. **CAUTION:** AVOID the use of prophylactic topical antibiotic ointments such as silver sulfadiazine, betadine or polymyxin-neomycin-bacitracin on the tissue around the driveline exit site as these ointments can injure the tissue.
35. **CAUTION:** DO NOT pull, kink or twist the driveline or the power cables, as these may damage the driveline. Special care should be taken not to twist the driveline while sitting, getting out of bed, adjusting controller or power sources, or when using the shower bag.
36. **CAUTION:** ALWAYS keep all connectors free of liquid, dust and dirt, or the HeartWare® System may not function as intended.
37. **CAUTION:** DO NOT attempt to repair or service any components of the HeartWare® System. If HeartWare® System equipment malfunctions, contact HeartWare.
38. **CAUTION:** DO NOT place batteries in water or liquid.

6.0 POTENTIAL COMPLICATIONS

Implantation of a Ventricular Assist Device (VAD) is an invasive procedure requiring general anesthesia, a median sternotomy, a ventilator and cardiopulmonary bypass. These surgical procedures are associated with numerous risks. Adverse events that may be associated with the use of the HeartWare® System are listed below. Other than death, the adverse events are listed in alphabetical order.

- | | | |
|------------------------------------|---|------------------------------|
| • Death | • Hemolysis | • Peripheral thromboembolism |
| • Air embolism | • Hepatic dysfunction | • Platelet dysfunction |
| • Aortic insufficiency | • Hypertension | • Psychiatric episodes |
| • Bleeding, perioperative or late | • Interference with/from other devices | • Renal dysfunction |
| • Cardiac arrhythmias | • Local infection | • Re-operation |
| • Death | • Multi-organ failure | • Respiratory dysfunction |
| • Device malfunction | • Myocardial infarction | • Right ventricular failure |
| • Device thrombosis | • Neurologic dysfunction | • Sensitivity to aspirin |
| • Driveline infection | • Organ damage during driveline tunneling | • Sepsis |
| • Driveline perforation | • Pericardial effusion/tamponade | • Stroke |
| • Driveline wire damage | | • Worsening heart failure |
| • Erosions and other tissue damage | | • Wound dehiscence |
| • GI bleeding/ AV malformations | | |

7.0 CLINICAL TRIAL RESULTS

7.1 Pivotal Clinical Study Design

This was a multi-center, prospective, contemporaneous control trial. The trial was non-randomized and open label. Enrollment in the study is complete, subjects have all reached the primary endpoint as described and specified in the protocol, but follow-up of subjects is ongoing.

Subjects were consented for participation and then assessed against the inclusion and exclusion criteria for participation in the study and implantation of the HVAD® Pump. After the surgical recovery period, patients were allowed to leave the hospital if they met additional criteria for hospital discharge. Each patient was followed to 180 days, death, device explant for recovery, or cardiac transplantation, whichever occurred first.

Patient outcomes were compared to a contemporaneously treated cohort of patients as recorded in the Interagency Registry for Mechanical Assisted Circulatory Support (INTERMACS). All patients enrolled in the INTERMACS registry over the same enrollment period as the trial that met the control group inclusion and exclusion criteria comprised the control group.

7.2 Study Objectives

Primary Objective

The purpose of the HeartWare® Ventricular Assist System study was to evaluate the safety and effectiveness of the HeartWare® System in patients listed for cardiac transplantation with refractory, advanced heart failure at risk of death. The primary endpoint is success at 180 days which was defined as alive on the originally implanted device or transplanted or explanted for recovery. If explanted for recovery patients must have survived 60 days post-explant to be considered successful.

Effectiveness was measured by the primary endpoint. The proportion of study patients alive, transplanted, or explanted for recovery at 180 days was compared to the same proportion obtained from the INTERMACS registry cohort and tested for non-inferiority.

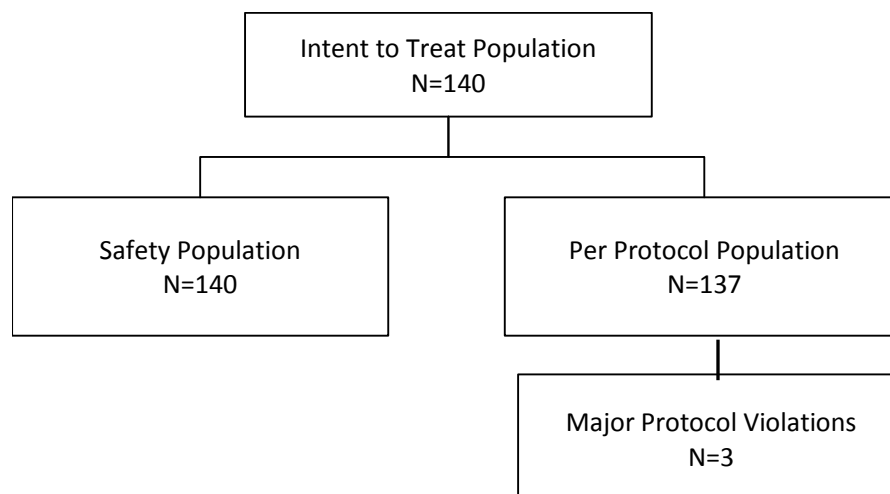
Secondary Objectives Including Safety

Secondary endpoints included: overall survival; incidence of all serious adverse events, including neurocognitive status and unanticipated adverse device effects; incidence of all device failures and device malfunctions; Quality of Life improvement, as measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ) and European Quality of Life Assessment (EuroQol) EQ-5D; and functional status improvement, as measured by New York Heart Association (NYHA) classification and 6-minute walk.

Safety measures included the frequency and rates of adverse events, overall and for each specific event, which were collected throughout HeartWare® System support.

7.3 Study Population Demographics and Baseline Parameters

There were three analysis populations defined for this trial. These are the intent-to-treat population, (ITT), the Safety population (SAF) and the Per Protocol population (PP).



Subjects were predominately male (72.1%) and 53.3 ± 10.3 years of age. BSA and BMI were 2.1 ± 0.3 kg/m² and 28.6 ± 6.1 m², respectively. The principal etiology of heart failure was ischemic heart disease (41%) and the average LVEF was 17.8 ± 7.1 %. Pulmonary Capillary Wedge Pressure (PCWP) was elevated at 23 ± 9 mm Hg and pulmonary artery pressures were also high: $(49 \pm 15)/(25 \pm 9)$ mmHg. The majority of patients were classified as NYHA IV (95%). Laboratory values at baseline were, in general, unremarkable except for an elevated BUN (26 ± 14 mg/dL) and a depressed hematocrit (34 ± 5.8 %).

Eighty percent of subjects in the HeartWare® System treatment group were on inotropic therapy at baseline. Some (23%) were on more than one inotrope. IABP therapy at baseline was reported for 25% of subjects and 85% presented with an AICD. Subjects received typical medications for congestive heart failure with diuretics (82%) most common.

Comparison of Selected Baseline Characteristics between Treatment and Control Groups

The mean age of implant recipients in the HeartWare® System group was 53.3 (range 22-70) and for the control, 52.2. Other parameters available to compare included gender, BSA, BUN, right atrial pressure and creatinine. In all cases, the values for both the HeartWare treatment and control groups were not statistically significantly different (Table 1).

Table 1: Select Baseline Characteristics for HeartWare and INTERMACS Groups

Characteristics	HeartWare® System N=140	INTERMACS N=499	p-value
Age (years)	53.3 ± 10.3	52.2 ± 12.2	0.19
Female Gender, n (%)	39 (28%)	120 (24%)	0.36
BSA (m ²)	2.06 ± 0.28	2.07 ± 0.30	0.59
BUN (mg/deciliter)	25.3 ± 13.5	28.9 ± 20.9	0.94
Right atrial pressure (mmHg)	10.8 ± 3.3	11.5 ± 5.0	0.53
Serum creatinine (mg/dL)	1.3 ± 0.4	1.4 ± 0.6	0.89

7.4 Safety and Effectiveness Results

EFFECTIVENESS RESULTS

Primary Endpoint

The analysis of the primary endpoint demonstrated HVAD® non-inferiority to the control group (Table 2). The difference in success rates between the HVAD® group and controls was less than the 15% non-inferiority margin ($p < 0.0001$). The 95% one-sided UCL on the difference in success rates was 4.5% for the Safety (SAF) population analysis and 0.9% for the Per Protocol (PP) population analysis. *The pre-specified primary endpoint was achieved.*

Table 2: Success Rates and Inference on non-Inferiority

	Implanted (N)	Successes N (%)	UCL (%)	p-value
Safety Cohort				
HVAD®	140	127 (90.7)	4.5	<0.0001
Controls	497	448 (90.1)		
Per Protocol Cohort				
HVAD®	137	126 (92.0)	0.9	<0.0001
Controls	497	448 (90.1)		

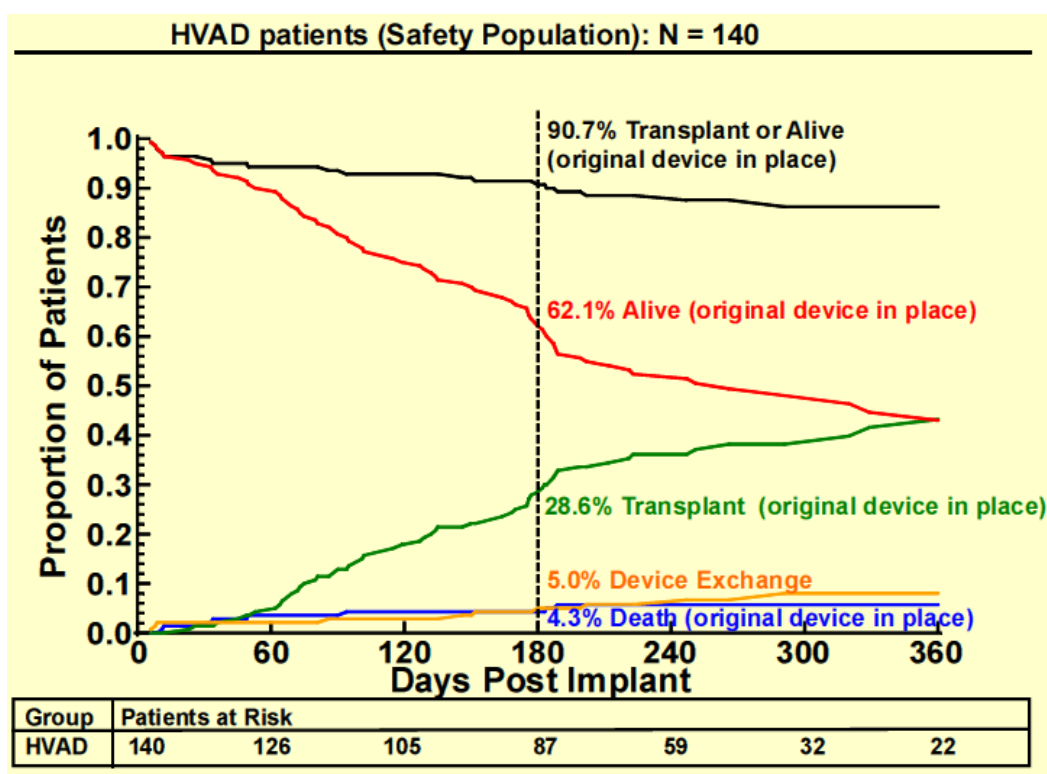
P-value: From significance test of non-inferiority

UCL: 95% one-sided upper confidence limit on the difference in success rates

Note: The table accounts for 497 of the 499 INTERMACS patients; the remaining 2 patients, who withdrew consent before 180 days, have a missing success/failure outcome.

Competing Outcomes

A competing risks analysis was performed (Figure 2), estimating the time-related probability of experiencing each of the component events. These data are calculated from all events occurring during the study duration, including deaths, transplants and exchanges occurring after 180 days but ending with last-patient, last-visit.

Figure 2: Competing Risk Outcomes (HVAD® Safety Population)

Deaths

There were eight subject deaths during the 180-day study period. Six deaths occurred in subjects with their originally implanted device and two deaths occurred after device exchange.

Safety Results

This study was not randomized and used a contemporaneous control for the sole purpose of comparing a pre-defined success outcome. The adverse events reported here are unique to the HeartWare® System and have no randomized comparator arm.

Exposure

The total support (exposure) on the original HeartWare® System was 20,698 days or 56.7 patient-years. The mean duration on device for the 140 subjects was 147.8 days (standard deviation 52.8) with a median 180 (range 6 – 180 days). The mean duration on study was 222.5 days (standard deviation 119) with a median of 196 (range 11 – 588 days). Duration on study exceeds duration on device, because the follow-up post-transplant is included.

Adverse Events

A total of 776 events (Table 3) were reported by investigators during the 180 day period on the original device. Of these 437 (437/776, 56.3%) were INTERMACS defined specific events, and 338/776 (43.6%) events were recorded under the INTERMACS category of "Other." One UADE was reported during the 180-day primary endpoint period.

Table 3: Summary of All Investigator-Reported Adverse Events

Event	Total	%
INTERMACS defined Events	437	56.3%
INTERMACS “Other” AE’s	338	43.6%
UADE	1	0.1%
Total	776	100%

INTERMACS Events

The INTERMACS defined adverse events for the 180-day primary endpoint on original device are summarized below and are separated into the perioperative (0-30 days) and post-perioperative (31-180 days) periods. Events meeting INTERMACS criteria are shown in Table 4 below. Bleeding, infections and arrhythmia were the most common. Most bleeding events qualified due to transfusions (see definition below). On the other hand, all reoperations due to bleeding were in the first 30-days post-op (23 vs. 0 events post-30 days).

Table 4: INTERMACS Events by Type and Time of Onset
(HeartWare® System N=140)

INTERMACS defined AEs	Day of Event Onset			
	0-30 Days		31-180 Days	
	Events N	Subjects N (%)	Events N	Subjects N (%)
BLEEDING				
Re op ¹	23	20 (14.3)	0	0
Transfusion criteria ² >4 units within 7 days	10	10 (7.1)	0	0
Any units at ≥ 7 days	31	25 (17.9)	46	20 (14.3)
Infections				
Local (non-device)	20	20 (14.3)	17	17 (12.1)
Driveline exit	5	5 (3.6)	14	11 (7.9)
Sepsis ³	3	3 (2.1)	8	7 (5.0)
Neurological Events				
Ischemic CVA	7	7 (5.0)	3	3 (2.1)
Hemorrhagic CVA	2	2 (1.4)	2	2 (1.4)
TIA	2	2 (1.4)	5	4 (2.9)
Respiratory Dysfunction	26	22 (15.7)	8	5 (3.6)
Arrhythmia				

INTERMACS defined AEs	Day of Event Onset			
	0-30 Days		31-180 Days	
	Events N	Subjects N (%)	Events N	Subjects N (%)
Ventricular	15	14 (10.0)	14	11 (7.9)
Supraventricular	25	21 (15.0)	7	6 (4.3)
Right Heart Failure				
Inotropes	17	17 (12.1)	8	7 (5.0)
RVAD	3	3 (2.1)	1	1 (0.7)
Arterial Thromboembolism	0	0	2	2 (1.4)
Venous Thromboembolism	4	4 (2.9)	3	3 (2.1)
Renal Dysfunction	8	8 (5.7)	6	5 (3.6)
Psychiatric event	5	5 (3.6)	4	4 (2.9)
Myocardial Infarction event	0	0	1	1 (0.7)
Hypertension	1	1 (0.7)	0	0
Hepatic dysfunction	3	3 (2.1)	1	1 (0.7)
Hemolysis event³	1	1 (0.7)	1	1 (0.7)

¹4 procedures were not included: elective hysterectomy, elective repair of hemorrhoids, HVAD® exchange and RVAD placement.

²Transfusion criteria include: $\geq 20\text{cc/kg}$ packed red blood cells (PRBC) within any 24 hour period during the first 7 day post implant and any transfusion of packed red blood cells (PRBC) after 7 days following implant with the Investigator recording the number of units given.

³Two cases were excluded: 1 case hemolysis < 72 hours post-implant; 1 case hemolysis occurring in the presence of tPA/Integrilin for VAD thrombosis

The majority of infections did not involve the driveline or cause sepsis. The local, non-device category encompasses a host of sites, including the urinary tract, lungs, sinuses, IV punctures, colon and skin. Infections involving the driveline exit site were more common after hospital discharge (> 30 days). Similarly, subjects were somewhat more likely to experience sepsis from 31-180 days (5.0% of subjects) than perioperatively (2.1%). Nearly a third (11/32) of the supraventricular arrhythmias were bouts of atrial fibrillation, requiring drug therapy. Nearly all the ventricular arrhythmias were ventricular tachycardia. AICD shocks were recorded in 24/29 episodes of ventricular arrhythmia and 2/29 received external cardioversion. Nearly all patients with a reported episode of ventricular tachycardia were subsequently placed on amiodarone.

Respiratory problems were more common in the perioperative period, declining from 26/34 events at 0-30 days to about one-third that number (8/34) from 31-180 days. Subjects were more likely to experience right heart failure events in the perioperative period (20/29). The most common treatment for right heart failure was the use of inotropic drugs and the pulmonary vascular dilator, nitric oxide (25/29). Three subjects required an RVAD and a fourth was exchanged for a pneumatic biVAD at 75 days post-implant. Ischemic strokes (ICVA) were more common overall (10/14 events) and occurred with greater frequency in the perioperative period (7/9 perioperative strokes). Four hemorrhagic strokes (HCVA) were recorded. Three of these resulted in deaths. TIAs were more common in the 31-180 day period (5/7 TIA events). While HCVAs were generally fatal (75%) they were most often associated with hypertension (MAP > 90 mm Hg). Three of the 4 HCVAs had a mean arterial pressure of ≥ 95 mm Hg at the time of the stroke and the one normotensive patient was septic and had an INR of 2.7 (high normal range).

Overall 70% of the patients who experienced ICVAs were transplanted or remained eligible. It is noteworthy that 6/10 ICVA events occurred within 48 hours of implant and may have been related to surgical procedural factors, such as ragged coring of the myocardium for inflow insertion or incomplete device de-airing. These issues were addressed by improvements to the coring tool and by site retraining. The overall stroke survival for the combined ICVAs and HCVAs on the original device was 77% (10/13 patients).

Venous thrombosis occurred in 5% of subjects. Most of these were cases of DVT in the lower extremities. In the arterial thromboembolism category, a case of VAD thrombosis was treated with tPA and resolved and in another case a clot was removed from the left main coronary artery following cardiac catheterization. A third case appeared to involve a shower of small emboli to the periphery.

No subject required permanent dialysis. Psychiatric events were recorded for nine subjects (6.4%). All recovered without sequelae. Two hemolysis events were detected by strict INTERMACS criteria in the absence of VAD thrombosis. These resolved spontaneously.

One subject experienced a myocardial infarction and one subject had a hypertensive event during the perioperative period. Hepatic dysfunction was noted in four subjects.

Adverse events were generally more common in the perioperative period.

SERIOUS ADVERSE EVENTS

A total of 452 serious adverse events on the original device occurred in 118 (84.3%) subjects (Table 5). A total of 287 INTERMACS defined events met the definition of an SAE, and 164 INTERMACS “other” events met the definition of an SAE.

Table 5: Summary of Serious Adverse Events (HeartWare® System N=140)

Serious Adverse Events (SAEs)	Number of SAEs	Subjects N (%)
Total Serious Adverse Events	452	118 (84.3)
INTERMACS	287	98 (70.0)
“Other”	164	75 (53.6)
UADE	1	1 (0.7)

Device Exchange

Device exchange occurred in 7 patients (7/140, 5.0%) in the SAF population during the period 180 days post-implant. Of these 7 exchanges, 3 were resultant from retained tissue being pulled into the pump from the ventricle in the very early post-operative period and were deemed to be procedure related, 2 were exchanged due to thrombus inside the pump, one was exchanged for a high power event of unknown cause and one due to latent right heart failure which caused the patient to require a biventricular support system.

Device Malfunctions

A device malfunction is defined as a failure of one or more of the components of the HeartWare® System, which either directly causes or could potentially, cause or induce a state of inadequate circulatory support (low cardiac output state) or death. There was information on 26 malfunctions from 20 subjects entered into the clinical database during the study period (Table 6).

Table 6: Malfunctions by Suspected Component

HeartWare® System N=140 Device Component ID	Events N (%)
LVAD	7 (5.0) *
Controller	7 (5.0)
Battery	1 (0.7)
Battery Charger	0
Monitor	0
Driveline	2 (1.4)
Controller AC Adapter	6 (4.3)
Other Component	3 (2.1)

*Described in Pump Exchange section

Neurological Events

This section contains certain neurological event data available on the HeartWare Ventricular Assist System. A comparison of the bridge-to-transplant clinical trial data to that published by Miller, et al.¹ and Pagani, et al.² is shown below. Comparisons of the adverse events recorded in HeartWare trial patients implanted with non-sintered HVAD® pumps through August 23, 2010 and in the perioperative period are shown in Tables Table 7 and Table 8 respectively. August 23, 2010 corresponds to the date of the last enrolled patient's last visit.

Table 7: HeartWare BTT Neurological Event Rates Compared to Literature

	HeartWare BTT		Miller et al.		Pagani et al.	
	Subjects Affected %	Events PPY [‡]	Subjects Affected %	Events PPY	Subjects Affected %	Events PPY
Overall		0.28		0.45		0.28
TIA	4.3	0.08	3.8	0.10	2.1	0.04
ICVA	7.1	0.12	6.8*	0.15	5.7*	0.09
HCVA	4.3	0.07	2.3	0.05	3.2	0.05
Other	0.7	0.01	6.0	0.16	5.3	0.09

[‡] Event rates for the HVAD® were calculated using 84.9 patient years.

* Includes one spinal cord infarct event.

Table 8: HeartWare BTT Early Neurological Event Rates Compared to Literature

	Patients Affected (%)			Event Rate (events PPY)		
	0-30 Days			0-30 Days		
	HW	Miller	Pagani	HW [‡]	Miller	Pagani
ICVA	5.0	3.8	2.8	0.63	0.49	0.37
HCVA	1.4	1.5	1.4	0.18	0.20	0.18
TIA	1.4	1.5	1.1	0.18	0.20	0.14
Other	0.7	2.3	1.4	0.09	0.29	0.18

[‡] Event rates for the HVAD® were calculated using 11.2 patient years.

¹ Miller et al. New England Journal of Medicine; August 30, 2007

² Pagani et al. Journal of the American College of Cardiology; July 21, 2009

A higher level of perioperative ischemic stroke events was seen with the HeartWare System in this initial cohort of patients. Forty percent of the ischemic stroke patients were ultimately transplanted. Thirty percent of ischemic stroke patients lost transplant eligibility while thirty percent were alive and remained eligible for transplant. One hundred percent of the hemorrhagic stroke patients died or lost transplant eligibility as a result of these neurological events.

During the continued access phase (CAP), data was captured on patients receiving HVAD® pumps with sintered inflow cannula. This device modification is incorporated in the PMA approved, commercial device and is intended to allow for increased tissue ingrowth around the inflow cannula. The stroke incidence in patients receiving these devices is lower than that of patients receiving devices with the non-sintered inflow cannula. The adverse event information for the CAP patients who received sintered versus non-sintered cannula pumps is shown below.

Table 9: Perioperative Neurologic Events for Sintered vs. Non-Sintered Pumps in CAP Cohort

INTERMACS Category Adverse Events	Sintered (N = 60)			Non-Sintered (N = 132)		
	(0-30 Days) Pts	(0-30 Days) % Pts	Events (0-30 Days)	(0-30 Days) Pts	(0-30 Days) % Pts	Events (0-30 Days)
Ischemic CVA	0	0.0	0	4	3.0	4
Hemorrhagic CVA	2	3.3	2	3	2.3	3
TIA	0	0.0	0	2	1.5	2

Table 10: Late Neurologic Events for Sintered vs. Non-Sintered Pumps in CAP Cohort

INTERMACS Category Adverse Events	Sintered (N = 60)				Non-Sintered (N = 132)			
	Pts	% Pts	Events (0 – 30 Days)	Events (> 30 Days)	Pts	% Pts	Events (0 – 30 Days)	Events (> 30 Days)
Ischemic CVA	2	3.3	0	2	11	8.3	4	7
Hemorrhagic CVA	4	6.7	2	2	10	7.6	3	9
TIA	1	1.7	0	1	3	2.3	2	1

A multivariate analysis³ was performed to identify the most significant factors associated with at least one stroke (ICVA and HCVA) event, and a stroke mitigation strategy was developed. To mitigate the risk of stroke with HVAD® pumps, clinicians should adhere to the following patient management guidelines:

- Maintain MAP at <85 mm Hg as tolerated. The HVAD® pump is sensitive to both preload and afterload
- Ramp speed and flows more slowly during the first few weeks (e.g., 30 days) post-implant to avoid excessive hemodynamic forces that may damage fragile blood vessels that have undergone remodeling secondary to the lower pressures and reduced flow associated with medically-treated heart failure. There is no apparent need to exceed a cardiac index of 2.6 L/min/m² until patients have fully recovered from the implant surgery and physical performance improves. A cardiac index of 2.6 L/min/m² is the lower limit of normal for a healthy adult.
- Maintain anticoagulation within the recommended INR range of 2.0-3.0.
- Check for ASA resistance with a reliable test (e.g., VerifyNow) and adjust ASA mono-therapy accordingly or consider combination therapy such as ASA 81 mg plus Aggrenox (ASA plus extended-release dipyridamole) or daily ASA 81 mg plus Plavix 75 mg. In general, mono-therapy with ASA is not encouraged in the absence of testing for resistance.

³More than thirty dichotomous covariates were considered as critical risk factors. Each covariate was assessed independently as a predictor (univariate analysis) and covariate influence was measured with odds-ratios and accompanying p-values using the Cochran-Mantel-Haenszel test. Covariate reduction was performed based on univariate analysis results and the impact of potential multicollinearity. In addition, important interaction terms were considered. A logistic regression analysis was performed with the remaining covariate terms to generate a model for predicting stroke outcomes.

ADDITIONAL CLINICAL DATA

Additional clinical data have been collected on the HeartWare VAS from an ongoing, randomized, controlled destination therapy trial (ENDURANCE) that should complete follow up in May 2014. Destination Therapy is for patients with end-stage heart failure who are 10 years older on average and not eligible for cardiac transplantation. Although the ADVANCE trial evaluated patients who were candidates for heart transplant, ENDURANCE does provide concurrent control adverse event information in a set of heart failure patients receiving mechanical circulatory support.

A subset of the unadjudicated data from ENDURANCE up to 180 days following implant is included in

Table 11. Of the patients who were implanted as of the cutoff date of May 6, 2012, 82 of 178 sintered HVAD® patients (46.1%) and 91 of 140 Control patients (65.0%) had been implanted at least 180 days prior to the cutoff date. Since pumps with sintered inflows are the only pumps marketed under this PMA by HeartWare, results for these HVADs are compared to the control device.

**Table 11: Select Adverse Events from ENDURANCE Trial to 180 days Post-Implant
(Data cut-off May 6, 2012)**

Site Reported Event (0-180 Days)	HVAD Sintered [% (n/N)]	Control [% (n/N)]
Death	14.0 (25/178)	13.6 (19/140)
Neurological events		
ICVA	6.7 (12/178)	4.3 (6/140)
HCVA	5.1 (9/178)	0.0 (0/140)
TIA	2.2(4/178)	2.9(4/140)
Device Exchange	3.9 (7/178)	5.7 (8/140)
Device Thrombus	2.8 (5/178)	7.1 (10/140)
Exchange	1.7 (3/178)	5.7 (8/140)
Med. Treated	1.1 (2/178)	1.4 (2/140)
Bleeding		
Bleeding requiring re-operation	11.8 (21/178)	12.9 (18/140)
Bleeding requiring transfusion ≥ 4 units within 7 days post implant	15.2 (27/178)	19.3 (27/140)
Infection	27.0 (48/178)	30.0 (42/140)

SECONDARY ENDPOINTS:

Overall survival in the HeartWare group was 94.3% (132/140) in the safety population and 91.2% in the control group at 180 days, as displayed in Table 12.

Table 12: Overall Survival at 180 days

	HeartWare® System N=140	INTERMACS N=499
Survival at 180 Days	N (%)	N(%)
Safety Population		
Survival	132/140 (94.3)	455/499 (91.2)
Died	8/140 (5.7)	44/499 (8.8)
Per Protocol Population		
Survival	130/137 (94.9)	455/499 (91.2)
Died	7/137 (5.1)	44/499 (8.8)

Survival differs from the primary analysis of success in that subjects who have a device exchange are not censored at the time of exchange, but continue to accrue time until the endpoints of transplant, death or explant for recovery.

QUALITY OF LIFE: KCCQ AND EUROQOL

Kansas City Cardiomyopathy Questionnaire (KCCQ): At baseline, 128/140 (91.4%) patients were able to complete the KCCQ and at month 6 there were 88 patients available to complete the test (39 had received a transplant, six had died, seven had met an endpoint receiving a device exchange) (Table 13). Of the 88 patients available for assessment, 74 patients had data at month 6, Reasons for missing the month 6 data included: 9 of 14 with poor compliance/missed visit (8 of 9 of these from a single site and 1 of 9 had a prior ICVA with MRS score of 2), 2 were too sick, 1 had no form available, 1 had been transplanted within the 14 day visit window, and 1 had refused. Seventy patients (70) had both baseline and month 6 data. For these 70 patients who were on HVAD® therapy continuously for 180 days had a 31 point improvement in KCCQ Overall Summary Score, over the 180 day period.

Table 13: KCCQ - Overall Summary Score

KCCQ	Baseline	Month 6	Change from Baseline
N	128	74	70
Mean (SD)	34.9 (18.9)	67.5 (20.4)	30.9 (26.5)
Median	31.5	71.4	34.5
Min, Max	0.0, 84.1	19.3, 100.0	-49.4, 80.5
95% CI	31.6, 38.2	62.8, 72.2	24.6, 37.3

European Quality of Life (EuroQol): At baseline, 130/140 (92.9%) of patients were able to complete the test, and at month 6 there were 88 patients available to complete the test, (39 had received a transplant, six had died, seven had met an endpoint receiving a device exchange) (Table 14). Of the 88 patients available 75 had data at month 6. Reasons for missing the month 6 data included: 9 of 13 with poor compliance/missed visit (8 of 9 of these from a single site and 1 of 9 had a prior ICVA with MRS score of 2), 2 were too sick, 1 had been transplanted within the 14 day visit window, and 1 had refused. Seventy-two patients (72) had both baseline and month 6 data showing an improvement of 30 points over the 180 day period.

Table 14: EuroQol (EQ-5D) - Summary of Quality of Life

EuroQol	Baseline	Month 6	Change from Baseline
Overall Summary Score			
N	130	75	72
Mean (SD)	39.7 (23.5)	69.8 (19.8)	29.5 (25.2)
Median	40.0	75.0	30.0
Min, Max	0.0, 92.0	4.0, 100.0	-36.0, 80.0
95% CI	35.6, 43.7	65.2, 74.4	23.6, 35.4

FUNCTIONAL ANALYSES: 6 MINUTE WALK

6 Minute Walk: Of the 132 patients assessed for the 6-minute walk test, the mean distance walked was 89.4 meters. Seventy-Five (75) of the 88 patients on pump at month 6 completed the test (Table 15 and Figure 3). Reasons for missing the 6 minute walk test at month 6 included: 9 of 14 with poor compliance/missed visit (8 of 9 of these from a single site and 1 of 9 had a prior ICVA with MRS score of 2), 2 were too sick, 1 had no form available, 1 had been transplanted within the 14 day visit window, and 1 had refused. These 75 patients showed a mean distance walked of 246 meters, a mean change of 150 meters from baseline.

Table 15: Functional Status – 6 Minute Walk

6 Minute Walk	Baseline	Month 6	Change from Baseline
Distance Walked in Meters			
N	132	75	74
Mean (SD)	89.4 (141.3)	246.0 (203.9)	150.1 (214.1)
Median	0.0	274.0	108.3
Min, Max	0.0, 600.2	0.0, 991.8	-273.1, 700.9
95% CI	65.1, 113.7	199.1, 292.9	100.5, 199.8

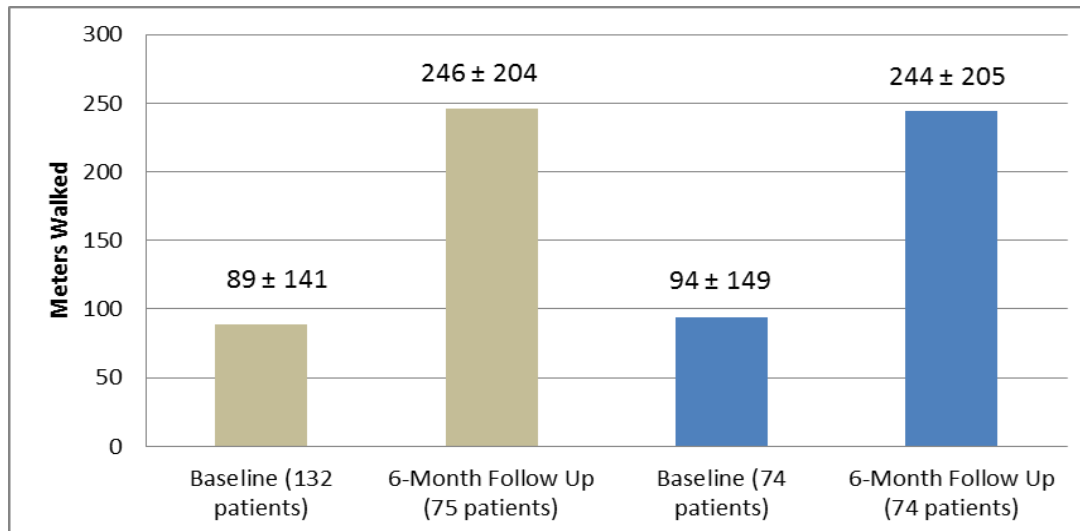
Figure 3: 6 Minute Walk Test

Table 16 shows a breakdown of results of patients who walked at both baseline and at 6 months as well as those patients that did not walk at baseline but did walk at 6 months.

Table 16: 6 Minute Walk – Breakdown of Patients Walking vs. Not Walking at Baseline

HeartWare® System Patients	Baseline (m)	Month 6 (m)
Patients walking at baseline and at 6 months	260 ± 140 (n=25)	338 ± 202 (n=25)
Patients NOT walking at baseline (for any reason) but walking at 6 months	N/A	333 ± 125 (n=30)

7.5 Overall Conclusions from Clinical Data

The HeartWare® System bridge-to-transplant study (ADVANCE) was a multi-center, prospective, contemporaneous control trial. The purpose of this study was to evaluate the safety and effectiveness in patients listed for cardiac transplantation with refractory, advanced heart failure at risk of death. The primary endpoint was success at 180 days which is defined as alive on the originally implanted HVAD® Pump or transplanted or explanted for recovery.

The analysis of the primary endpoint yielded non-inferiority of the HeartWare® System to the INTERMACS control. The 95% one-sided UCL on the difference in success rates was 4.5% for the Safety Group and 0.9% for the Per Protocol Group. Each of these limits was less than the 15% non-inferiority margin (p-value <0.0001).

- *The pre-specified primary endpoint was achieved.*
- *Both quality of life and functional capacity showed improvements following implant of the HVAD® Pump.*
- *The HeartWare System has an adverse event profile that supports its safe use for bridge to transplant patients.*

8.0 SYSTEM COMPONENT OVERVIEW

See Appendix B for a complete list of system components.

8.1 HeartWare® Ventricular Assist System

The HeartWare® System consists of a blood pump with an integrated, partially sintered inflow cannula; a 10mm diameter gel impregnated polyester outflow graft, and a percutaneous driveline. A strain relief is used on the outflow graft to prevent kinking and secures the outflow graft to the pump. The driveline cable is wrapped with woven polyester fabric to encourage tissue in-growth at the skin exit site. The small, wearless pump has a displaced volume of 50cc and weighs 160 grams. The pump has one moving part, an impeller, which spins blood to generate up to 10 L/min of flow. There are two motors in the pump housing with one motor providing redundancy. A short integrated inflow cannula is inserted into the left ventricle and the outflow graft connects the HVAD® Pump to the aorta. A sewing ring attaches to the myocardium and allows for pump orientation adjustments intraoperatively. The device size and short inflow cannula allow for pericardial placement, which eliminates the need for abdominal surgery and device pockets (Figure 4).

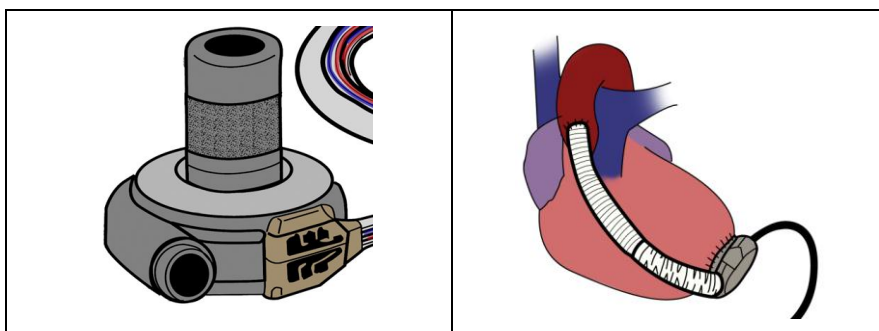


Figure 4: HVAD® Pump and left ventricular (LV) cannulation

8.2 HeartWare® Controller

The controller (Figure 5) is a microprocessor unit that controls and manages HeartWare® System operation. It sends power and operating signals to the blood pump and collects information from the pump. The percutaneous driveline is connected to the controller, which must always be connected to two power sources - an AC adapter or DC adapter and/or rechargeable batteries. The controller's internal, non-replaceable, rechargeable battery is used to power an audible "No Power" alarm when both power sources are disconnected. The controller interfaces with the monitor through a data port.



Figure 5: Controller

1. Monitor Connection
2. Power Connection
3. Driveline Connection
4. Power Connection

CAUTION: ONLY use HeartWare® Controllers on one patient to avoid risks associated with an inadvertent mismatch of controller pump speed settings.

8.3 HeartWare® Monitor

The monitor (Figure 6) is a touch screen tablet that uses proprietary software to display system performance and to permit adjustment of selected controller parameters. When connected to a controller, the monitor receives continuous data from the controller and displays real-time and historical pump information. The monitor also displays alarm conditions.

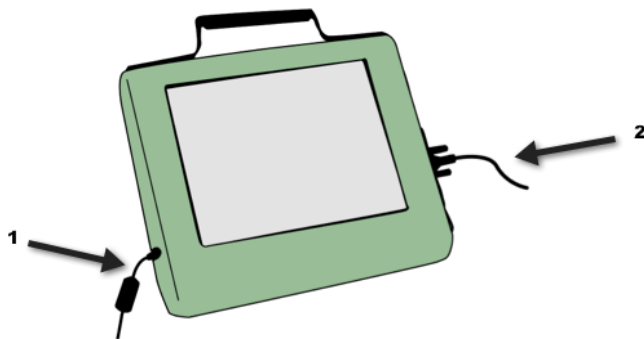


Figure 6: Monitor

1. Power Cord
2. Monitor/Controller Connection

8.4 HeartWare® Controller Power Sources

The controller requires two power sources for safe operation: either two batteries, or one battery (Figure 7) and an AC adapter (Figure 8) or DC adapter (Figure 9). While active, patients will typically use

two batteries. While relaxing or sleeping, patients should use power from an electrical outlet (AC adapter) because it provides power for an unlimited period of time. The batteries should be exchanged when their charge falls below 25% capacity. Spare, fully charged batteries should always be available.

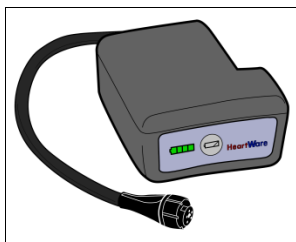


Figure 7: Battery

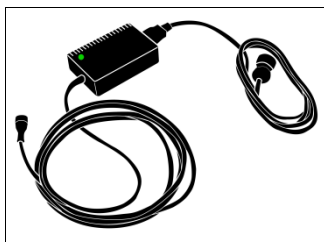


Figure 8: AC adapter

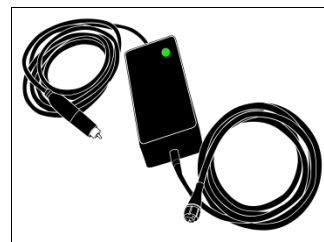


Figure 9: DC adapter

WARNING! NEVER disconnect both power sources (batteries and AC or DC adapter) at the same time since this will stop the pump. At least one power source must be connected at all times.

8.5 HeartWare® Battery Charger

The battery charger (Figure 10) is used to simultaneously recharge up to four batteries. It takes approximately 4 to 5 hours to fully charge a depleted battery.

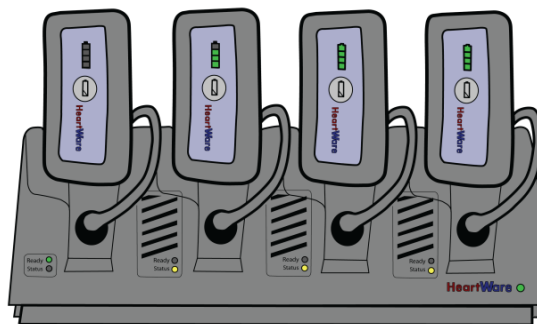


Figure 10: Battery charger

8.6 Equipment for Implant

Figure 11 shows the HeartWare® System components used at implant (provided ETO sterilized).

- **HVAD® Pump**
- **Outflow graft** – a 10mm diameter gel impregnated graft
- **Strain relief** – to prevent outflow graft kinking
- **Sewing ring**– to secure the HVAD® Pump to the left ventricle
- **Driveline cap** – to protect the driveline connector when tunneling
- **Inflow cap** – to cover the pump inflow cannula after the wet test and prior to implantation

- **Driveline extension cable** - used during the pre-implant wet test to keep the non-sterile controller isolated from the sterile field

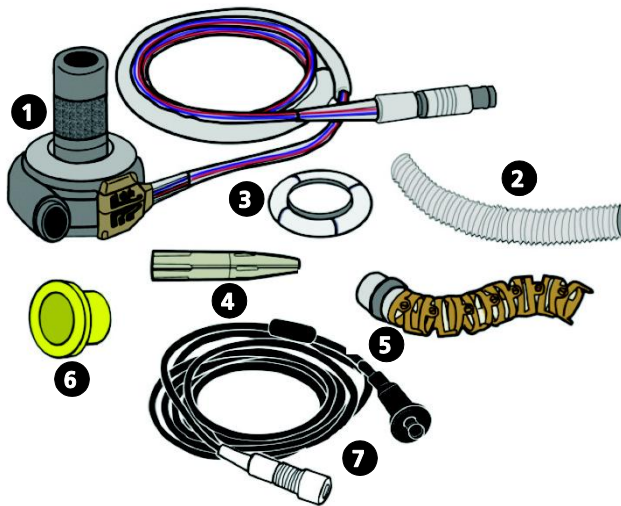


Figure 11: Components used at implant

1. HVAD® Pump
2. Outflow graft
3. Sewing ring (made of titanium and polyester)
4. Driveline cap
5. Strain relief
6. Inflow cap
7. Driveline extension cable

A set of surgical tools (provided ETO sterilized) is also required for implantation of the device (Figure 12).

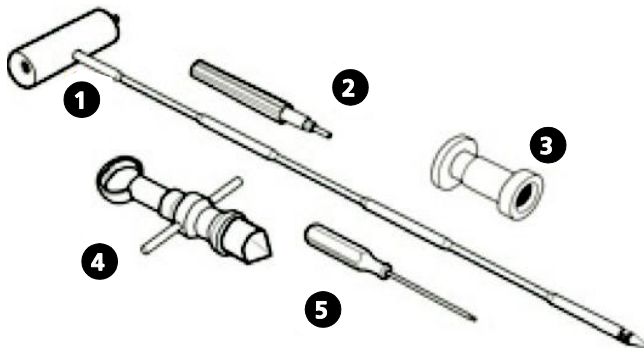


Figure 12: Surgical tools

1. **Tunneler** – to tunnel the pump's percutaneous driveline through the skin to the exit site
2. **Sewing ring wrench** – to tighten the screw on the sewing ring
3. **Driveline cover** – to cover the driveline connection to the controller
4. **Apical coring tool** – to core the LV apex
5. **Hex driver** – to secure the strain relief and outflow graft to the HVAD® Pump

All tools and accessories used during implantation are for single-use only.

9.0 PRINCIPLES OF OPERATION

9.1 Background

Continuous flow pumps contain a rotating impeller that adds energy to the blood by converting the rotational kinetic energy into mechanical energy (Figure 13). Impeller blades push the fluid through the pump using hydrodynamic and centrifugal forces. The net effect is to build up the fluid pressure, sometimes referred to as pump head (i.e., related to the differential pressure across the device) or just head, such that the fluid is moved from the inlet to the outlet of the pump. Pump head is the difference between the afterload and the preload. Energy to rotate the impeller is provided through electromagnetic coupling between permanent magnets (rotor magnet) attached or enclosed within the impeller and the motor stators. The motor stators consist of coils of wire that are sequentially charged by electrical current, turning the coils into electromagnets. These electromagnets have the effect of spinning the rotor magnets around an axis of rotation. The HVAD® Pump is efficient at pumping moderate quantities of blood against moderate amounts of resistance.

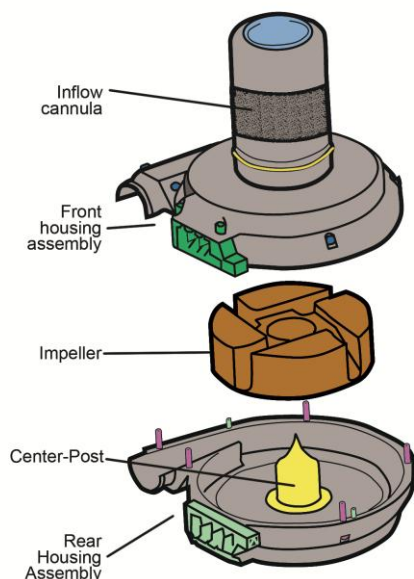


Figure 13: Exploded view of HVAD® pump

1. Inflow Cannula
2. Front Housing Assembly
3. Impeller
4. Center Post
5. Rear Housing Assembly

9.2 Blood Flow Characteristics

The amount of flow a rotary pump can generate is dependent upon the diameter of the impeller, the geometry of the impeller blades, housing design, motor capacity, rotational speed, and pressure differential that exists across the pump. This allows for in-vitro pump characterization for a specific pump and is the basis for blood flow estimation.

The HeartWare® System estimates blood flow rate using HVAD® Pump characteristics (electrical current, impeller speed) and blood viscosity. Viscosity is calculated from the patient's hematocrit. To obtain the most accurate estimate of blood flow, the patient's hematocrit must be entered into the HeartWare® monitor. Flow estimation should be used as a trending tool only, as it cannot adapt to changing fluid conditions (see Section 9.3.1, Flow Estimation).

The volume of flow generated by the HVAD® Pump is determined by the rotational speed of the impeller and by the pressure differential across the pump. The pressure that the HVAD® Pump must work against is similar to the mean arterial pressure. If the pump speed (RPM) is set too low then the device may not generate enough forward pressure. This can lead to retrograde flow (flow from the aorta back through the device and into the left ventricle). The maximum rotational speed is determined by how much flow is available from the right heart. If the speed is set too high and the pump attempts to pump more blood than is available, ventricular suction may occur.

The controller operates in "Fixed" mode, which maintains a constant motor speed. The motor speed range is between 1800 and 4000 RPM. The appropriate speed should be determined based on the patient condition.

NOTE: Recommended HVAD® Pump speeds are between 2400 RPM and 3200 RPM. HVAD® Pump speeds outside this range may result in less than optimal HVAD® Pump operation.

9.3 Physiological Control Algorithms

The HVAD® Pump control algorithms provide clinicians information about device performance and HVAD® Pump blood flow estimation.

9.3.1 Flow Estimation

Estimated HVAD® Pump blood flow is calculated using VAD power, speed parameters, and hematocrit, based on a blood sample from the patient. The default hematocrit setting is 30%, but for accurate flow estimation, the patient's hematocrit should be entered into the monitor. Adjustments to the hematocrit setting on the monitor should be made for hematocrit changes of $\pm 5\%$ or greater.

NOTE: Update hematocrit settings on the monitor whenever hematocrit changes by plus or minus 5% or more.

The valid range of estimated blood flow is -2 to 10 L/min. The table below shows monitor and controller display messages and what they mean.

Monitor and Controller Display	Estimated Flow Range
--	Invalid, not available
< -2 L/min	less than -2.0 L/min
-2.0 L/min up to 10.0 L/min	-2.0 to 10.0 L/min
> 10 L/min	greater than 10 L/min

The error of the estimated flow is the maximum of either 1 L/min or 20%, whichever is greater. Flow estimation accuracy can be maintained only if accurate hematocrit values are entered.

Out of range values on the low side (less than -2.0 L/min), are invalid in terms of estimated flow but could indicate an incorrect hematocrit value used in the flow calculation. Out of range values on the high side (greater than 10 L/min), may occur due to thrombus or other materials (e.g. tissue fragments) in the device or due to an incorrect hematocrit value used in the flow calculation.

NOTE: Flow estimation should only be used as a trending tool. Actual flow may differ from readout due to variability of patient's hematocrit.

WARNING! DO NOT rely only on flow estimation to assess cardiac output. An average estimated flow on the monitor or controller display of less than 2 L/min, or greater than 10 L/min may indicate an electrical fault, incorrect hematocrit entry or an occlusion due to thrombus or other materials (e.g. tissue fragments) in the device. Inaccurate assessment of HVAD® Pump flow may lead to less than optimal treatment.

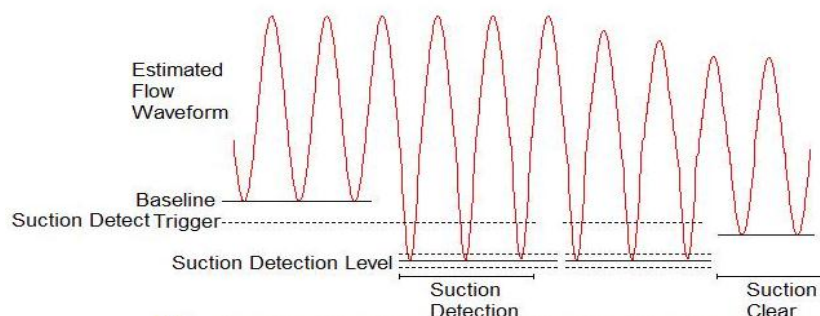
9.3.2 Ventricular Suction Detection Alarm

A suction condition may occur due to ventricular collapse or inflow occlusion. Ventricular collapse occurs when a continuous flow VAD attempts to pump more blood from the left ventricle than is available, resulting in considerable reduction in ventricular volume. Left ventricular collapse can be the result of clinical events affecting left ventricular preload, including hypovolemia (bleeding), right heart failure, arrhythmia or pulmonary embolus. An inflow occlusion occurs when the inflow cannula is obstructed, causing a suction condition. Temporary inflow obstruction can occur as a result of surgical positioning, patient position or during straining (Valsalva).

The ventricular suction detection alarm functions by monitoring the estimated flow for sudden decreases in flow rate. A flow baseline is established by continuously tracking the minimum flow

values. A trigger value is established at 40% below the estimated flow baseline. An indication of suction is obtained when the minimum flow falls below this trigger level. The alarm will be triggered if this condition is maintained for 10 seconds.

The flow minimum that triggers the suction alarm is also used to define the suction clear limit. The estimated flow baseline is continuously compared to this limit. The suction alarm will be cleared if the flow baseline is maintained above the trigger level for 20 seconds. This is an indication that the suction condition has cleared.



The ventricular suction detection alarm can only be activated from the System Screen of the monitor. Therefore, only the clinician has access to control the state of this alarm. The default setting for Suction Response is off. In this mode, there will be no alarm during a ventricular suction condition. An “Sx Off” message will be displayed on the lower left-hand corner of the monitor screen below the “Fixed” mode display. When Suction Response is enabled (via the “Alarm” button), the “Sx On” message will be displayed on the lower left-hand corner of the monitor screen below the “Fixed” mode display.

NOTE: Whether or not the ventricular suction detection alarm is enabled (“Sx On”) or is off (“Sx Off”) can only be determined with the monitor; it cannot be determined from the controller.

The Suction Response “Alarm” mode must not be turned on if the patient is in a suction condition. If the mode is turned on during a suction condition, the “Sx On” message will be displayed on the monitor and the ventricular suction detection alarm will be enabled but will be inaccurate due to the fact that normal baseline parameters could not be established during a suction condition. The algorithm attempts to establish a baseline detection level to distinguish abnormal conditions. This is not possible if the patient is experiencing ventricular suction when the algorithm is initiated. Once the suction condition clears, an accurate baseline will be obtained automatically and the suction detection will proceed.

NOTE: Ventricular suction detection may be activated once the patient’s intravascular volume and pump flow have been stabilized.

If a ventricular suction detection alarm is triggered, the clinician should evaluate whether the alarm was triggered by a transient, reversible condition which corrects itself, or whether the alarm is more serious and requires intervention. Transient alarms often occur at certain times during the day and/or under particular circumstances such as bending over or lying on one side. They usually resolve quickly without problems. If the ventricular suction detection alarm is persistent and there are clinical symptoms of decreased blood flow, such as dizziness or hypotension, or if a “Low Flow” alarm is active, then the patient should be evaluated. This can be accomplished by checking the pump flow waveform on the monitor for evidence of suction, or if necessary, by visualizing the left ventricle with

echocardiography. Next, the clinician should attempt to identify and treat the underlying cause of the suction event. If the cause for the suction event cannot be determined, or if the cause is refractory to treatment, then the clinician should manually adjust the speed to resolve the suction condition under echocardiographic guidance. Manual changes to the speed will immediately disable the ventricular suction detection alarm. An “Sx Off” will be displayed on the monitor screen below the “Fixed” Mode display. The clinician will have to reactivate the alarm after adjusting the speed.

CAUTION: Manual changes to the speed will immediately disable the ventricular suction detection alarm. An “Sx Off” will be displayed on the monitor screen below the “Fixed” mode display. The ventricular suction detection alarm will have to be re-activated.

CAUTION: DO NOT enable the ventricular suction detection alarm while the patient is in a suction condition. To optimize operation of the suction detection the patient should be hemodynamically stable prior to enabling the ventricular suction detection alarm.

The ventricular suction detection function will temporarily deactivate if:

- The estimated flow value becomes invalid. Once the flow estimation is within valid range, the ventricular suction detection will resume.
- The baseline flow value is less than 1.8 L/min – the algorithm loses sensitivity if the baseline and, therefore, the suction detection level gets too low. Once the baseline value is above 1.8 L/min, then the ventricular suction detection will resume.
- The clinician changes the hematocrit input – the algorithm recognizes that a change in the fluid viscosity will cause a change in the estimated flow. The ventricular suction detection reactivates once a new baseline is established.

9.4 HVAD® Pump Operating Guidelines

The HVAD® Pump speed can be set between 1800 and 4000 RPM, however the recommended clinical operating speed range is 2400 to 3200 RPM. Speeds below 2400 RPM should only be used during the implant procedure when weaning from cardiopulmonary bypass. Speeds above 3200 RPM are seldom needed and increase the risk of suction events. HVAD® Pump power ranges from 2.5 to 8.5 watts when operating within the recommended speed range. Power values > 8.5 watts suggests a problem which should be evaluated by log file analysis. The table below shows the expected average values for speed, power and flow at 2400 and 3200 rpms.

Table 17: Expected Average HVAD® Pump Parameters

Speed (rpms)	Power (watts)	Flow (L/min)
2400	2.5	3
3200	8.5	8

One of the operating goals for the HVAD® Pump is to maintain device operation in the “Normal Pulsatility Region” to avoid retrograde flow and suction events. HVAD® Pump flow pulsatility is the difference between the minimum (trough) and maximum flows which are displayed in the flow waveform on the HeartWare® Monitor. Pulsatility is reflected in a positive waveform (similar in form to an arterial line waveform) where the trough value represents the flow during left ventricular diastole and the peak value represents the flow during left ventricular systole (see Figure 14 below). Pulsatility is affected by a number of patient conditions including left ventricular contractility, right heart function and left ventricular afterload.

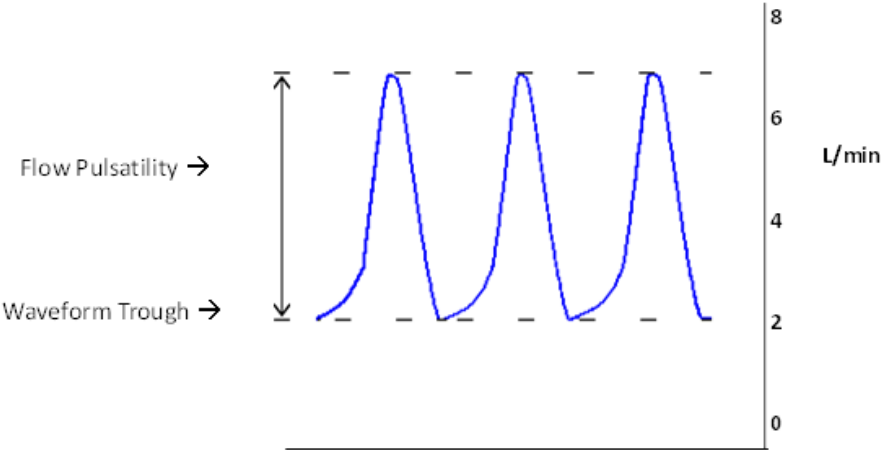


Figure 14: HVAD® Pump flow waveform

The flow waveform trough is the minimum value of the HVAD® Pump flow waveform. The trough value should be > 2 L/min and there should be > 2 L/min of pulsatility. An example of a flow wave form with a trough of > 2 l/min and pulsatility of > 2 L/min is shown below.

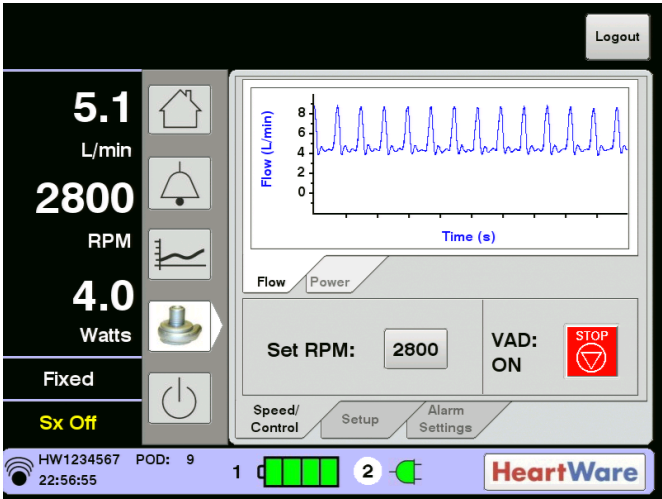


Figure 15: HeartWare® Monitor screen showing HVAD® Pump flow waveform

10.0 USING THE HEARTWARE® MONITOR

To turn the monitor ON, press and hold the power button until the monitor software starts up. The power button is located on the top of the monitor (Figure 16):

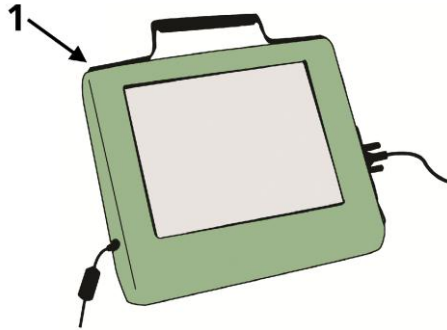


Figure 16: Monitor Power Button (1)

The monitor is designed to provide a user-friendly way to monitor and control the HeartWare® System. The monitor:

- Displays pump information
- Allows users to adjust pump parameters
- Monitors and reports system errors and alarm conditions

CAUTION: ALWAYS fully charge the monitor's internal battery prior to patient use.

CAUTION: DO NOT allow patients to touch the monitor, as this may lead to the entering of unwanted HeartWare® System parameters.

The monitor is designed to use AC power from a wall outlet. The monitor can also use its internal battery during patient transportation. Keep the monitor's battery charged by connecting the monitor AC adapter to an electrical outlet at all times – even while in storage. It takes approximately 4 hours to charge a depleted battery. If the monitor is going to be stored for a long period, removing the battery and leaving the monitor unplugged is also an option.

NOTE: The monitor should always use AC power except during patient transport.

There are five icons (Figure 17) on the monitor to access system information and to manage pump operation. The icons are displayed on all screens. When an icon is selected, it points to the screen.



Figure 17: HeartWare® Monitor screen icons

Pump parameters are displayed along the left-hand side of all monitor screens. Parameters displayed include average pump blood flow (L/min), speed (RPM) and power (Watts) (Figure 18). The top of the monitor screen displays alarm messages for active controller alarms. The alarm messages are identical to those displayed by the controller. During active alarms, the Alarm Mute icon appears on the top right of the monitor screen. Pressing this icon silences the alarm for 5 minutes. The upper section of the monitor screen also displays status messages.

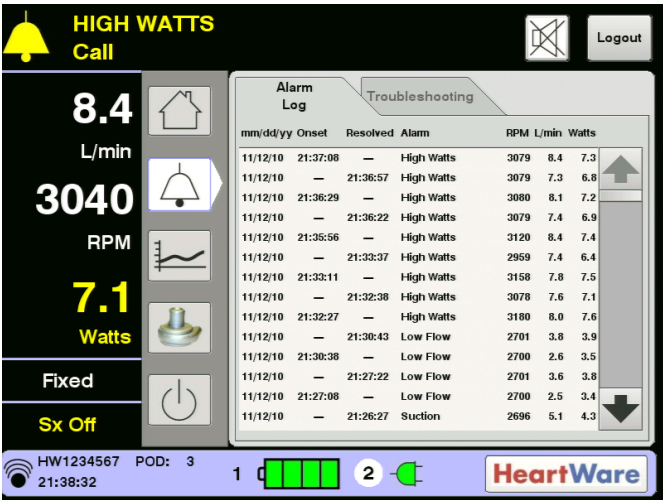



Figure 18: Monitor screen layout

The bottom of each screen includes the controller data download status icon, patient identification, time, postoperative day (POD) and power supply status. Either the “1” or “2” will light to indicate which source is powering the controller. The illuminated “2” in Figure 19 indicates that an AC or DC adapter is connected to power supply connector 2 and is operating the controller. The remaining battery capacity is also displayed for battery power. If one of the power sources is disconnected, the corresponding icon disappears.



Figure 19: Power supply indicators

10.1 Clinical (Home) Screen

Press the Home  Icon to access the Clinical screen.

The Clinical Screen (Figure 20) displays a real-time power (Watts) waveform and a real-time estimated HVAD® Pump blood flow waveform (L/min). Waveform time scales may be selected for 10 seconds, 20 seconds, or 60 minutes.

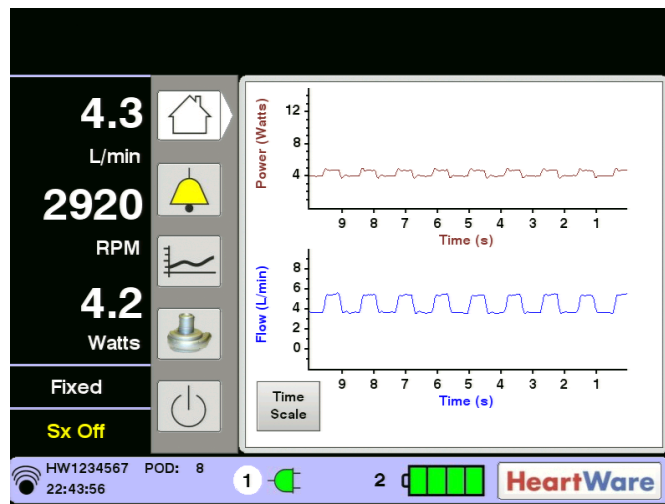



Figure 20: Clinical Screen

10.2 Alarm Screen

The Alarm Screens (Figure 20 and Figure 21) are accessed by pressing the Alarm  Icon.

- A WHITE Alarm Icon is displayed for no alarms or for a low priority alarm.
- A YELLOW Alarm Icon indicates an active or resolved medium priority alarm.
- A RED Alarm Icon indicates an active or resolved high priority alarm condition.

If there are multiple alarms, the Alarm Icon will indicate the highest priority alarm. The Alarm Icon will not return to a white color until the icon is pressed after resolution of the alarm condition.

The Alarm Screen has two tabs (Alarm Log and Troubleshooting). The Alarm Log (Figure 21) provides access to the alarm information. The controller is designed to store 200 alarm entries on a first-in first-out basis. The Alarm Log displays the date and time when each high or medium priority alarm occurs and when the alarm resolves. Pump parameters are also displayed next to the alarm.




Figure 21: Alarm Log

The Troubleshooting tab displays active high and/or medium priority alarms and potential causes for each alarm (Figure 22). Low priority alarms are not displayed in the Troubleshooting tab.



Figure 22: Troubleshooting tab

10.3 Trend Screen

The Trend Screen (Figure 23) is accessed by pressing the Trend Screen  Icon.

Waveform trend data is accessed on the Trend Screen by pressing the Flow/Speed tab or Flow/Power tab. Flow (L/min) and speed (RPM), or flow (L/min) and power (Watts) can be displayed. Use the Display Interval button to select between the following time intervals: 60 minutes, 4 hours, 24 hours, 14 days or 30 days.

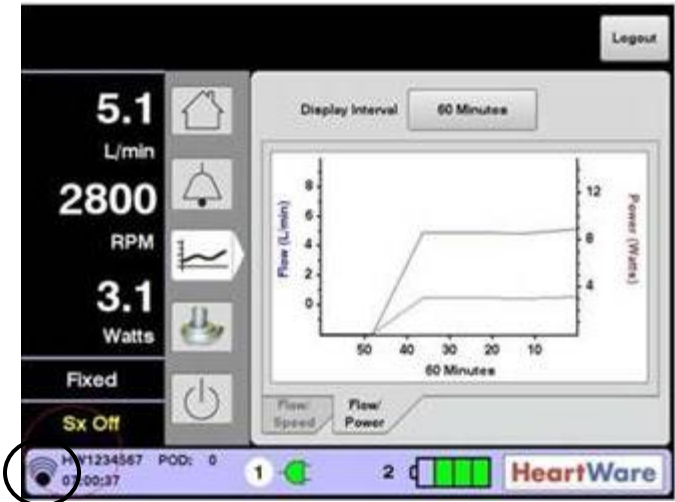



Figure 23: Trend Screen

Trend data is uploaded from the controller to the monitor by connecting the monitor data cable to the controller (see section 10.4.2.1.1 Downloading Controller Log Files).

10.4 System Screen

The System Screen is accessed by pressing the HVAD® Pump  Icon.

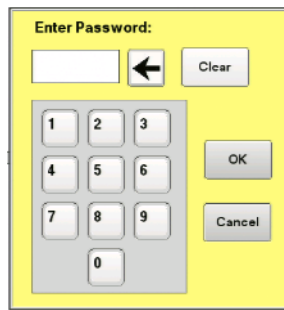


Figure 24: Password Dialog Box

The System Screen is password-protected. HeartWare will provide the clinician with a password. The dialog box (Figure 24) is used to enter the numeric password. User access is timed out after 11 minutes of non-use.

10.4.1 Speed/Control Tab

The System Screen displays waveforms with real-time estimated flow (L/min) or real-time power (Watts). The preferred waveform is selected by pressing the Flow or Power tab (Figure 25).

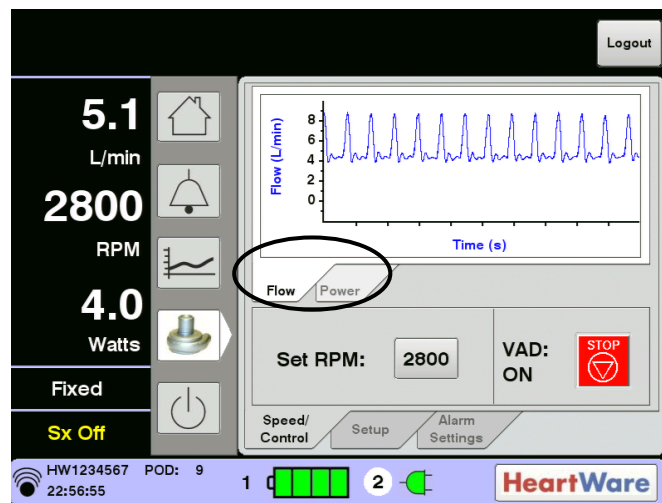


Figure 25: System Screen

The Speed/Control tab is used to adjust RPM and to turn the VAD on or off. The Set RPM button is used to adjust the pump speed (RPM) from 1800 to 4000 and the VAD button is used to turn the pump on and off. When the Set RPM button is pressed, a dialog box will appear with an up arrow and a down arrow. Pressing the up or down arrow will change the pump speed in increments of 20 RPM.

NOTE: After perioperative period, recommended pump speed during patient support is 2400 RPM to 3200 RPM.

Confirm the speed adjustment by pressing the change button. The HVAD® Pump button is colored and labeled according to the running state of the HVAD® Pump:

- VAD: ON means the HVAD® Pump is pumping; the button is RED and labeled STOP. To stop VAD, press STOP.
- VAD: OFF means the HVAD® Pump is NOT pumping; the button is BLUE and labeled START. To start VAD, press START (Figure 26).

- A dialogue box will appear prompting the user to confirm each action.

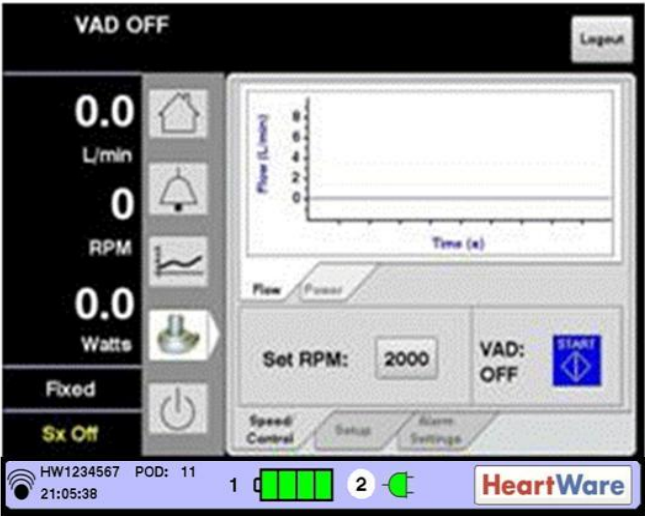


Figure 26: System Screen – VAD start

10.4.2 Setup Tab

When the Setup tab is pressed, four additional tabs are displayed and include: Patient, VAD, Controller and Monitor (Figure 27). The function of each is described below.

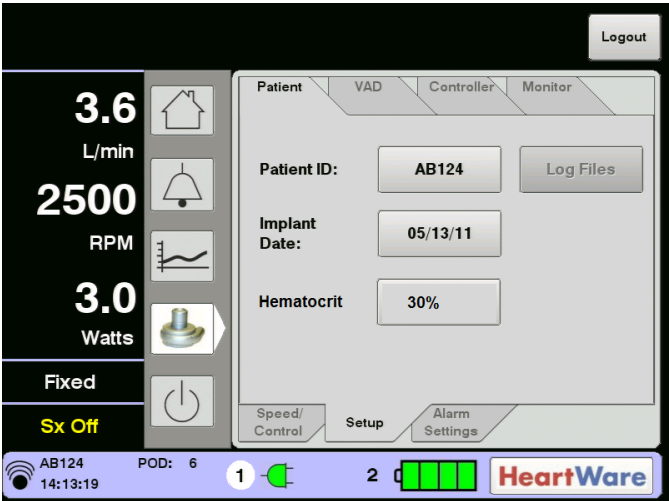


Figure 27: Setup tab

10.4.2.1 Patient Tab

The Patient tab is used to enter Patient ID, Implant Date and Hematocrit. Press the Patient ID to enter patient identification. The patient ID is entered by using the keypad (Figure 28). The A to Z and 0 to 9 tabs allow entry of numbers or letters.

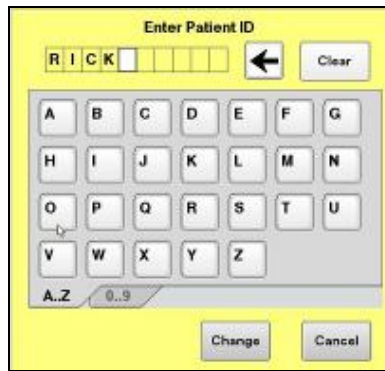


Figure 28: Patient ID dialog box

NOTE: Patient ID must be entered for patient's alarms to be displayed in the monitor's alarm log.

Press the Implant Date button and enter the HVAD® Pump implant date using the keypad. Use the Enter button to confirm entry or the Cancel button to cancel entry (Figure 29).

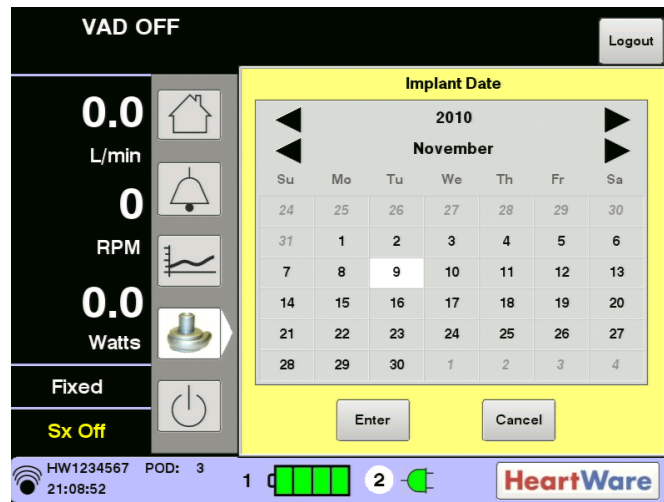


Figure 29: Implant Date Screen

The hematocrit can be changed using the Hematocrit (%) button (refer to Figure 27). This method allows the clinician to manually input the patient's hematocrit using a measurement obtained from a blood sample. The default hematocrit value is 30%.

10.4.2.1.1 Downloading Controller Log Files

The Log Files button allows the clinician to obtain alarm and trend data from the controller and to transfer it from the patient's controller to a USB flash drive.

Process for downloading log files from the controller

- Using the monitor data cable, connect the blue data port on the controller to the monitor.
- Check that the data download icon in the lower left hand corner of the monitor is flashing grey. The data download icon will become black when the download is complete. It may take up to 10 minutes for all the data to transfer from the controller to the monitor.
- Press the Pump Icon to access the System Screen and enter the password.
- Press Setup tab.

- Press Patient tab.
- Wait until the data download icon stops flashing and turns black then disconnect the monitor data cable from the controller.

NOTE: DO NOT disconnect the controller from the monitor when the data transfer icon is flashing, as data is being transferred. If the message, **“Log Transfer Not Complete!”** appears, re-connect the controller to the monitor to complete the data transfer.

- 5 seconds after disconnecting the data cable, the Log Files button will appear. Press this button and a list of the patient logs will be displayed.
- Place a HeartWare® Monitor compatible USB memory stick into the USB port on the left side of the monitor.
- Select the logs to be saved. Press the Save to USB button.
- A confirmation screen will appear to affirm selection. If correct, press YES button.
- A download complete message will appear when data download is complete. Press OK.
- Remove the USB stick and email the three files: data, alarm and events (3 separate files) to hvadlogs@heartwareinc.com.

NOTE: The maximum storage for each controller is 3000 entries, which equates to approximately 31 patient days. A USB flash drive can be used intermittently to download data.

10.4.2.2 VAD Tab

The VAD tab (Figure 30) is used to enable or disable the Suction Response and to enter the HVAD® Pump serial number. “Fixed” mode (manual entry of pump speed) is the only mode currently available, and therefore this button is disabled.

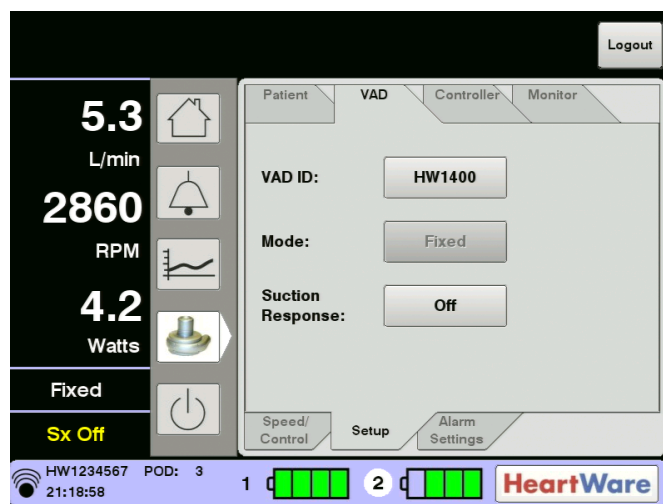


Figure 30: VAD tab

Press the VAD ID button to enter the HVAD® Pump serial number from the Implant Kit package. After pressing the VAD ID button, a dialog box is displayed (Figure 31) and the serial number is entered by using the keypad to enter letters and numbers. The first two letters of the VAD ID are fixed with the letters “HW”. After the information is entered, press the Change button. If an incorrect number is entered, press Cancel and start again.



Figure 31: VAD ID dialog box

The Suction Response button includes two options for suction detection:

- Suction Response “Off”. This is the default setting.
- Suction Response on with “Alarm”. An alarm will sound if a suction event is detected.

See section 9.3.2 (Ventricular Suction Detection Alarm) for more information on suction detection. When the pump speed is changed by accessing the Speed/Control tab, the dialog box reminds users that this will disable the suction detection alarm (Figure 32).

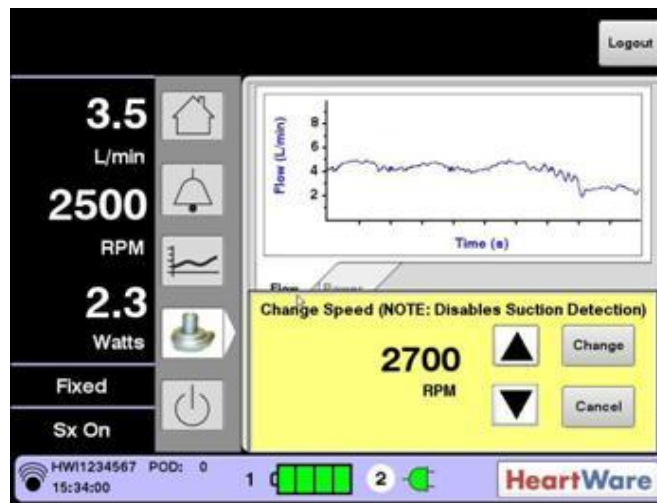


Figure 32: Dialog box for pump speed changes

10.4.2.3 Controller Tab

The Controller tab (Figure 33) allows the user to enter the controller date and time, set the controller default values, and activate the ‘Disable “VAD Stop” Alarm’ feature.



Figure 33: Controller tab

Press the Controller Date and Controller Time buttons to enter the controller date and time, respectively.

Set Defaults: The Set Defaults (Figure 34) button sets the controller parameters to the original manufacturer settings listed below:

- Set Speed is 2500 RPM
- Low Flow Alarm threshold is 1.0 L/min
- High Power Alarm threshold is 16 Watts
- Suction Response is "Off"
- Data Log Interval: 15 minutes
- Hematocrit is 30%

NOTE: A controller reset (removal of both power sources) is required following a "Set Defaults" command for the command to take effect.



Figure 34: Default setting

CAUTION: DO NOT use the “Set Defaults” button on the monitor when a controller is connected to a patient. Pressing it will erase all patient VAD parameter information from the controller.

Disable “VAD Stop” Alarm:

The purpose of this feature is to allow programming of a controller when it is not connected to a pump (or a motor fixture). After applying power to the controller, it will pause for ten seconds before detecting whether or not a pump is disconnected (a “VAD Stopped” condition). The Disable “VAD Stop” Alarm feature enables the user to send a command to the controller to tell it NOT to alarm when a pump is not attached. This allows the input of patient and controller information via the monitor without an audible alarm. This pending command will clear after 3 minutes.

Steps:

1. Press ‘Disable “VAD Stop” Alarm’ indicator on monitor (Figure 35)
2. Connect monitor to controller
3. Power up controller with 2 power sources
4. Enter patient and controller information via the monitor
5. Disconnect monitor from controller
6. Disable “No Power” alarm by pressing the Alarm Mute and Scroll buttons simultaneously for 5 seconds
7. Disconnect power from controller
8. The “VAD Stop” Alarm will be re-armed automatically after 3 minutes as long as the monitor is not connected to a controller (Figure 36)

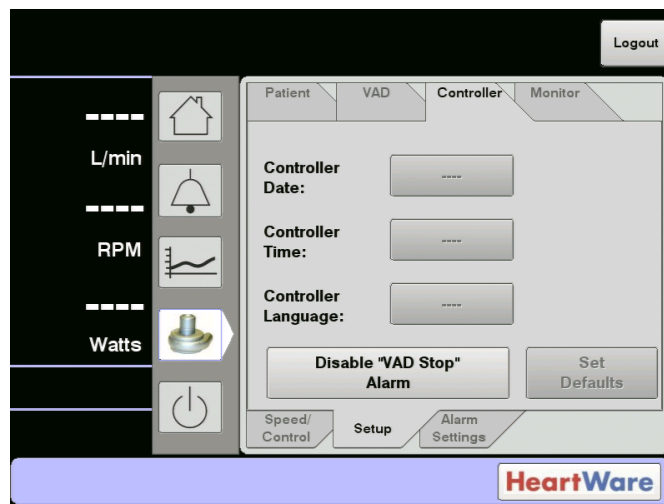


Figure 35: Disable “VAD Stop” Alarm

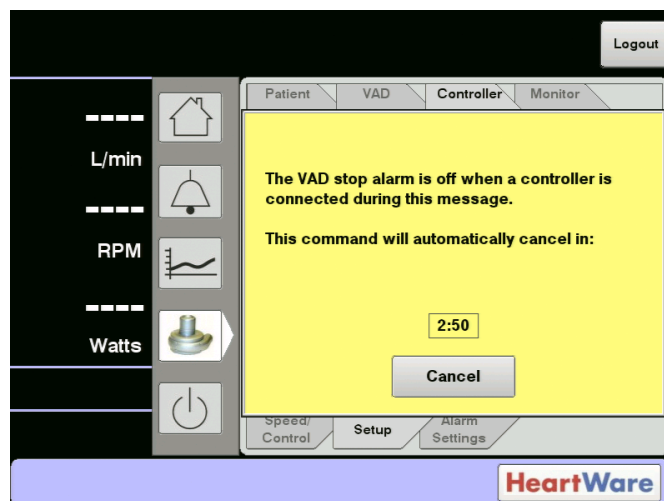


Figure 36: Pending VAD stop command

10.4.2.4 Monitor Tab

The Monitor tab is used to enter the date and time and to calibrate the monitor touch screen (Figure 37). This version of the HeartWare® Monitor supports English language only.

- **Monitor Date** and **Monitor Time**: These buttons set the date and time on the monitor.
- **Language**: Set to English.
- **Touchscreen**: Use this button to initiate touch screen calibration for the monitor. The monitor will only initiate the calibration sequence if the controller is NOT connected to the monitor.



Figure 37: Monitor tab

10.4.3 Alarm Settings Tab

The Alarm Settings tab (Figure 38) is used to set the Low Flow Alarm and High Power Alarm thresholds. Both flow and power are time averaged values not instantaneous values. The Low Flow Alarm threshold may be set from 1 L/min to 9.9 L/min in 0.1 L/min increments. The Low Flow Alarm should be set at 2 L/min below the patient's average flow. Do not set the Low Flow Alarm below 2 L/min. The High Power Alarm may be set from 1.0 Watts to 25.0 Watts in increments of 0.5 Watts. Default settings are 1 L/min

for Low Flow and 16 Watts for High Power. The High Power Alarm should be set 2 Watts above the patient's average power. If the flow drops below the low flow threshold (e.g. 1 L/min) or the power exceeds the high power threshold (e.g. 16 Watts), an alarm is triggered. Clinicians should set the Low Flow and High Power Alarm thresholds close to the patient's flow and power values, respectively.

NOTE: The Low Flow Alarm should be set at 2 L/min below the patient's average flow. DO NOT set the Low Flow Alarm below 2 L/min.

NOTE: The High Power Alarm should be set 2 Watts above the patient's average power.

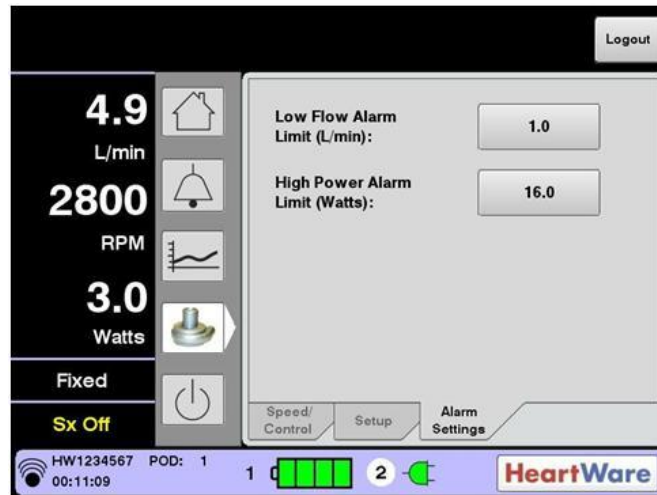


Figure 38: Alarm settings tab

When certain alarm or fault conditions exist, the Alarm Settings tab may be used to access additional controls to silence the audio component of the alarm or fault for extended time periods. The Controller Fault Audio button appears during a medium priority “Controller Fault” alarm (Figure 39). The Controller Fault Audio button can be used to permanently silence a controller fault alarm. However, the controller and monitor will continue to display the controller fault alarm until the condition resolves.

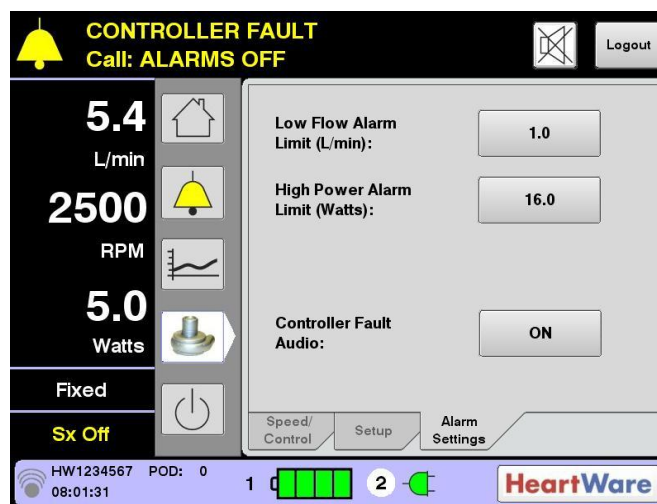


Figure 39: Controller fault audio

Permanently silencing the “Controller Fault” audible alarm is a two-step process. Pressing the “Silence” button on the monitor touch screen will bring up a confirmation box (Figure 40). Pressing the “Yes” button will silence all current medium priority controller fault alarms. Subsequent controller faults will produce new audible alarms.



Figure 40: Permanently silence controller fault dialogue box

The Electrical Fault Audio button appears during a medium priority “Electrical Fault” alarm (Figure 41). The Electrical Fault Audio button can be used to permanently silence an electrical fault alarm. However, the controller and monitor will continue to display the electrical fault alarm until the condition resolves.

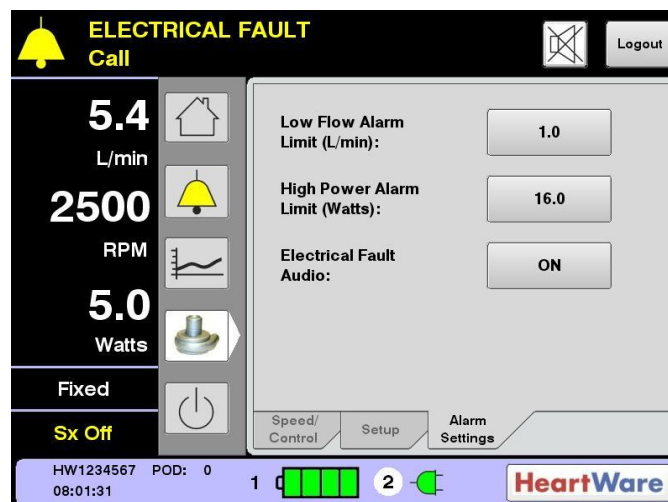



Figure 41: Electrical fault audio

WARNING! ALWAYS investigate, and if possible, correct the cause of any alarm. Silencing an alarm does not resolve the alarm condition.

The user should always log off the password-protected System Screens after completing system adjustments. Press the Logout button and confirm by pressing the Yes button to return to the Clinical

Screen. If the System Screen is not used for 11 minutes, the user is automatically logged out and needs to enter the password to access these screens.

10.5 Monitor Shut Down

The Monitor On/Off  Icon is used to shut down the monitor program.

NOTE: Always press the On/Off icon on the screen before pressing the power button on the top of the monitor or data may be lost.

A dialog box will appear after pressing the Monitor On/Off Icon asking you to confirm (Figure 42):

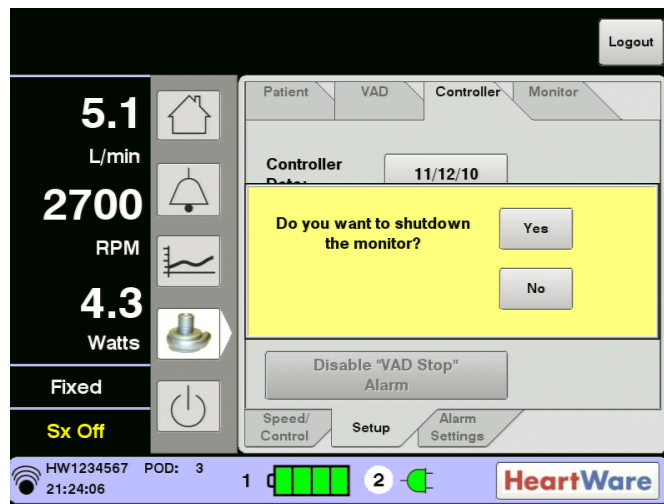


Figure 42: Confirming monitor shutdown

Press “Yes” to exit the program, and then press the power button/switch located at the lower left corner of the monitor when the “It is now safe to turn off power” prompt appears on the monitor.

OR

Press “No” to return to the program.

11.0 USING THE HEARTWARE® CONTROLLER

11.1 Controller Connector Layout

There are four connectors, two on either side of the controller (Figure 43). The power supply connections are identical and are used to connect to any of the power sources (batteries, AC adapter or DC adapter). The controller should always be connected to two power sources for safety. If only connected to one power source, the controller will function, but will sound an alarm after 20 seconds.

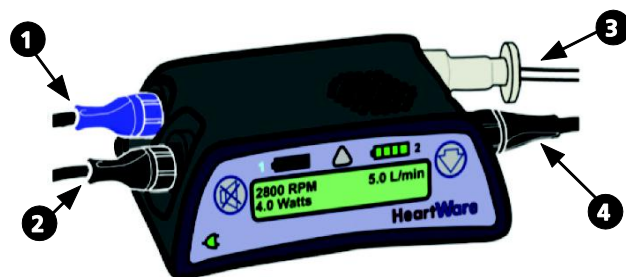


Figure 43: Controller
1. Monitor Connection
2. Power Connection
3. Driveline Connection
4. Power Connection

The driveline is connected to the silver connector. To connect the driveline to the controller, align the red markings on both connections and push together (Figure 44). The driveline cover should completely cover the controller's silver driveline connector to protect it and keep it clean. To disconnect the driveline, pull the driveline cover away from the silver controller connector, then pull the driveline connector from the silver controller connector.

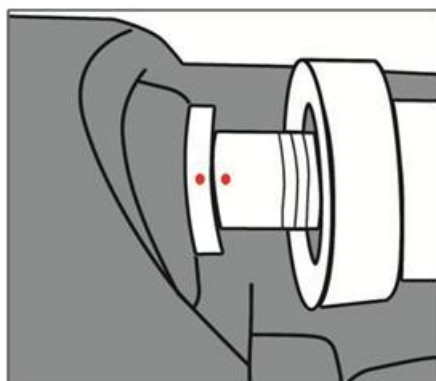


Figure 44: Driveline connection to controller

WARNING! DO NOT grasp the driveline cable as this may damage the driveline. To remove the driveline from the controller, first pull back the driveline cover then grasp and pull the driveline connector.

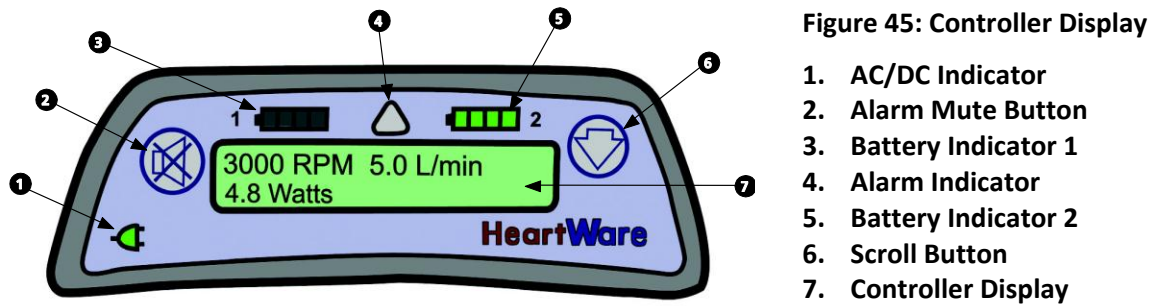
WARNING! DO NOT disconnect the driveline from the controller or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.

The monitor cable attaches to the blue data port connector on the controller. The monitor cable and power adapters have identical connectors and attach to the controller in the same way. To connect, align the white arrow with the white dot and push the two halves until the connector locking mechanism latches. To disconnect, twist the connector counterclockwise and pull the two connectors apart.

11.2 Controller Display and Operation

WARNING! DO NOT operate the controller in temperatures less than -20°C (-4°F) or greater than 50°C (122°F) or the controller may fail.

The controller face (Figure 45) incorporates a number of visual indicators and function buttons.



11.3 How to Change the Controller

A backup controller and fully charged batteries must be available at all times for controller failures or malfunctions. The backup controller should be set with the same pump parameters and patient information as the primary controller. A controller failure or serious controller malfunction will generate a high priority or RED alarm and the controller display will tell you if you should “Change Controller”.

To change the controller:

1. Have the patient sit or lie down.
2. Place the **new controller** within easy reach.
3. Connect backup power sources to the **new controller**.
 - Confirm that the power cables are properly locked onto the controller by gently pulling on the cable near the connector.
 - A “Power Disconnect” alarm will activate if a second power source is not connected to the **new controller** within 20 seconds of controller power up.
 - A “VAD Stopped” alarm will activate if the pump driveline is not connected to the **new controller** within 10 seconds. This alarm will resolve once the pump driveline is connected.
4. Pull back the white driveline cover from **original controller’s** silver connector (Figure 46).

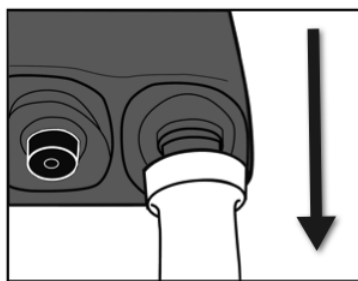


Figure 46: Remove white driveline cover

5. Disconnect the driveline from the **original controller** by pulling on the silver connector away from the controller. Do not disconnect by pulling on the driveline cable. A “VAD Stopped” alarm may activate.
6. Connect the driveline to the **new controller** (align the two red marks and push together) (Figure 47). If the “VAD Stopped” alarm was active on the new controller, it will now resolve.

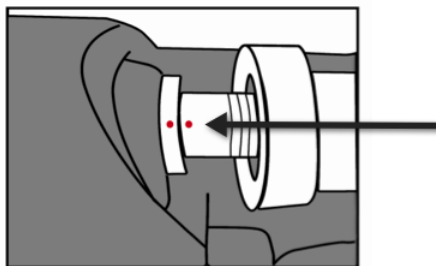


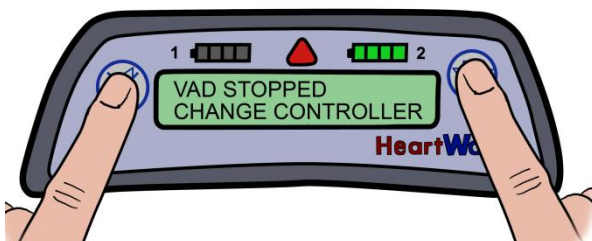
Figure 47: Connect Driveline to New Controller (align the two red marks)

- The pump should restart. The RPM, L/min and Watts numbers should show on controller display.
7. To prevent the controller alarm from sounding after the power is removed:
- **If a red alarm adapter is available**, insert it into the blue connector on the **original controller**.



WARNING! DO NOT attach the alarm adapter to a controller connected to the running pump. The alarm adapter silences the “No Power” alarm and should only be attached to a controller that has failed or malfunctioned and is no longer connected to a pump.

- **If no alarm adapter is available:**
 - Press and hold the Alarm Mute and Scroll Buttons simultaneously on the **original controller** until a “beep” is heard, or for at least 5 seconds.
 - Release the Alarm Mute and Scroll buttons.



8. Disconnect both power sources from the **original** controller. The controller will be turned off and all alarms silenced.

9. Slide the white driveline cover up to cover **new controller's** silver connector (Figure 48).

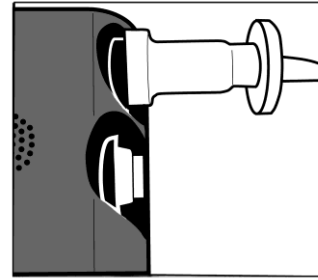


Figure 48: Replace driveline cover

10. Contact HeartWare to obtain a new backup controller.

WARNING! ALWAYS keep a spare controller and fully charged spare batteries available at all times in case of an emergency.

12.0 USING THE HEARTWARE® BATTERIES

The batteries (Figure 49) contain lithium ion cells to power the HVAD® Pump for approximately 4 to 6 hours when fully charged. The capacity (hours of support) of each battery is based on:

- Controller and HVAD® Pump operating power consumption
- Number of battery charge and discharge cycles

The batteries are expected to have a useful operating life of greater than 500 charge and discharge cycles. If a battery provides less than two hours of support duration, it should be replaced.

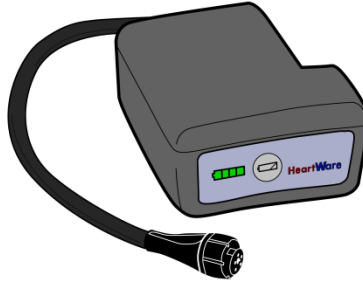












Figure 49: Battery

Battery Buttons and Indicators	
	Pressing the TEST BUTTON will light up the Battery Capacity Display.
	The BATTERY CAPACITY DISPLAY will tell you how much power remains in the battery.

The Battery Capacity Display on the battery is similar to the Battery Indicator on the controller (see Section 11.0 Using the HeartWare® Controller), except that only green lights are used on the battery. For example, at 25-49% capacity, 2 green lights will be displayed on the battery while 2 yellow lights will be displayed on the controller (see chart below).

Battery Capacity	Battery Capacity Display on BATTERY	Battery Indicator on CONTROLLER
75-100%	4 GREEN lights 	4 GREEN lights 
50-74%	3 GREEN lights 	3 GREEN lights 
25-49%	2 GREEN lights 	2 YELLOW lights 
≤24%	1 GREEN light 	1 RED light 

NOTE: When one battery is depleted to <25%, the controller will automatically switch to the other battery. When this happens, an intermittent “beep” will sound, the Alarm Indicator on the controller will be yellow, and a message will be displayed to replace the depleted battery (Figure 50).

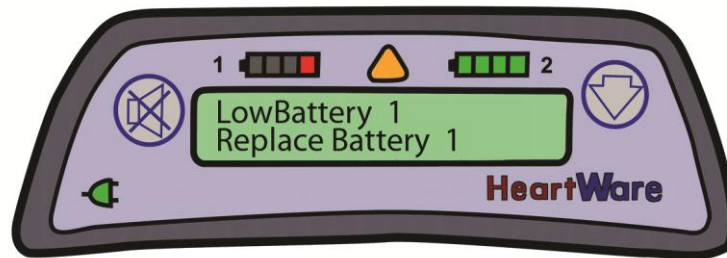


Figure 50: Replace depleted battery message on controller

If the battery is NOT changed within 5 minutes, the alarm volume will escalate until the battery is exchanged with a fully charged battery. When a depleted battery is not exchanged and there are only a few minutes of battery time remaining in both batteries, a high priority alarm will sound, the Alarm Indicator will flash RED and the message on the controller will display “Critical Battery 1” or “Critical Battery 2.” If this occurs, there are only a few minutes of power remaining before the pump stops; therefore, the batteries must be replaced immediately.

CAUTION: ALWAYS recharge fully depleted batteries within 24 hours to avoid permanent battery damage.

12.1 Changing a Battery

1. Make sure there is a fully charged battery available to replace the used or depleted battery.
2. Disconnect the depleted battery by turning the connector sleeve counterclockwise until it stops (follow arrow).
3. Pull the connector straight out from the controller.
4. Grasp the cable of the fully charged battery near the connector, leaving the connector free to rotate.
5. Line up the solid white arrow on the connector with the white dot on the controller (Figure 51A).

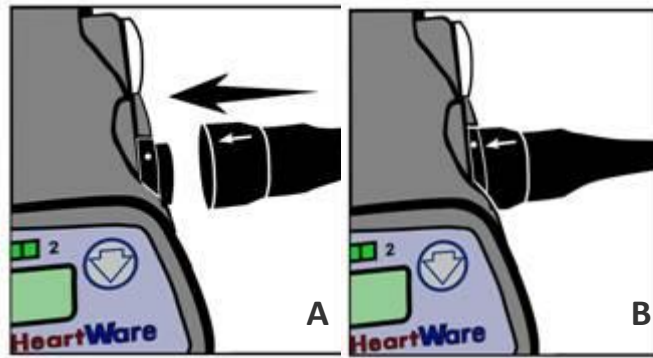


Figure 51: Connecting power to controller

6. Gently push the cable into the controller. DO NOT twist the connector, but allow it to naturally lock in place. A successful connection will result in an audible click.

NOTE: When pushing the connector onto the controller the white arrow will shift slightly. Correct locking position - white arrow aligned with white dot on controller (Figure 51B).

7. Confirm that the battery cables are properly locked on the controller by gently pulling the cable near the controller power connector.

CAUTION: DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.

CAUTION: ALWAYS confirm that the power cables are properly locked on the controller by gently pulling the cable near the controller power connector or the power cables may come loose and result in an alarm or the pump stopping.

12.2 Care of Batteries

1. To preserve battery life, batteries should be stored at room temperature.
2. Protect batteries from extreme high and low temperatures. Avoid storage in direct sunlight.
3. Protect the battery connectors from moisture, dirt and metal at all times.
4. Handle connectors so as to avoid touching the inside.
5. Do not drop the batteries or let them hit hard objects.
6. Do not let batteries get wet.
7. Do not twist or kink battery cables.
8. Do not force battery connection to the controller or battery charger.
9. Batteries should be stored in the battery charger. Store batteries fully charged.

CAUTION: DO NOT expose batteries to temperatures outside the storage and operational ranges or they may provide less support than usual. To preserve battery life, batteries should be stored at room temperature.

Battery operating and storage temperatures:

- a. Operating: discharge (normal use with the HeartWare® System) and charge (while on battery charger): 0°C to 45°C (+32°F to 113°F). Operation at temperatures below 0°C will **temporarily** reduce battery capacity but the battery will operate.
- b. Storage: -20°C to 25°C (-4°F to 77°F). Long term storage outside of this range may **permanently** reduce the battery capacity. Best condition for storage is at room temperature.

CAUTION: ALWAYS keep batteries away from children. Children may be harmed by damaged batteries or components.

CAUTION: DO NOT disassemble, crush, or puncture a battery.

CAUTION: DO NOT use a damaged battery. Battery function is unknown if the battery is damaged.

CAUTION: DO NOT short circuit the external contacts on a battery since this may result in battery damage.

CAUTION: DO NOT touch the fluid if a battery pack is leaking fluid. Dispose of a leaking battery pack. In case of eye contact with fluid, DO NOT rub eyes. Immediately flush eyes thoroughly with water for at least 15 minutes, lifting upper and lower lids, until no evidence of the fluid remains. Seek medical attention.

CAUTION: DO NOT expose batteries to excessive shock or vibration since this may affect battery operation.

CAUTION: DO NOT dispose of a battery in fire or water. Dispose of batteries according to federal, state, and local regulations.

13.0 USING THE HEARTWARE® BATTERY CHARGER

The battery charger (Figure 52) can charge up to 4 batteries at a time. It takes approximately 4 to 5 hours to fully charge a depleted battery. The battery charger must be plugged into a properly grounded electrical outlet to charge batteries. The power indicator is green when the battery charger is properly connected to electrical power. Each battery slides into a bay and is connected to the battery charger. It is safe to leave the batteries in the charger and the charger plugged into a wall outlet at all times.

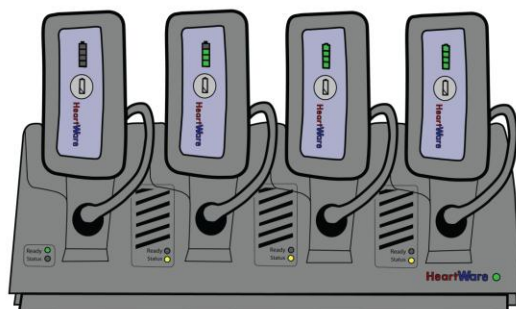
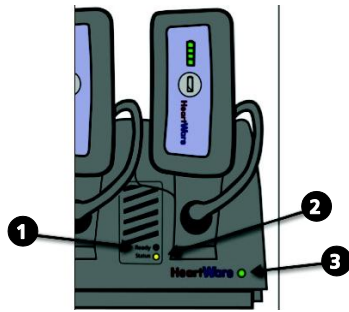


Figure 52: Battery charger

The charger has two indicators for each charging bay. The indicators are “Ready” and “Status.” The green light adjacent to the “Ready” indicates that the battery is fully charged (Figure 53).

**Figure 53: Battery charger indicators**

1. Ready
2. Status
3. AC Power

Battery Charger “Status” Light	What it Means
Yellow	Battery being charged; NOT ready for use.
Flashing Yellow	Battery not charging. Check battery connections. If connections are intact, switch to another battery slot. If problem persists, return battery to HeartWare.
Red	Battery too cold or too hot; waiting to charge.
Flashing Red	Defective battery. Do NOT use. Mark battery and return to HeartWare.

CAUTION: ONLY use the HeartWare® Battery Charger to charge HeartWare® Batteries. Other battery chargers will not charge the batteries and may damage them.

CAUTION: ALWAYS wait until the “Ready” light turns on to disconnect the battery from the battery charger. If this is not followed over consecutive charging cycles, the Battery Capacity Display will not function properly and may convey misleading battery capacity.

13.1 Connecting the Battery to the Battery Charger

1. The battery connects to the battery charger the same way that it connects to the controller.
2. Grasp the cable of the battery near the connector, leaving the connector free to rotate.
3. Line up the solid white arrow on the connector with the white dot on the battery charger.
4. Gently push the cable onto the battery charger until it locks in place.

13.2 Disconnecting the Battery from the Battery Charger

1. Disconnect the charged battery by turning the connector counterclockwise until it stops.
2. Pull the connector straight out from the battery charger.

14.0 USING THE HEARTWARE® CONTROLLER AC ADAPTER OR DC ADAPTER

The AC adapter (Figure 54) has cables that connect to the controller and into an electrical outlet. Prior to connection to the controller, verify proper connection of the power cord to the adapter (Figure 55) and electrical outlet. If not properly connected, perform the following steps:

1. Using a Philips screw driver, loosen the screw at the retainer clip to allow the retainer clip to open.
2. Insert the AC power cord completely and securely into the receptacle of the AC adapter.
3. Tighten the screw at the retainer clip closing the retainer clip.
4. Ensure that AC power cord is secure in the adapter receptacle and cannot be pulled out.

A green indicator light on the adapter will indicate proper connection. Ensure that the power indicator on the power adapter cable turns green before plugging into the controller.

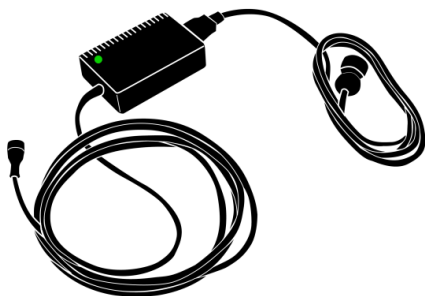


Figure 54: AC adapter



Figure 55: Power cord connection

The DC adapter (Figure 56) plugs into the power port located in most cars. When the DC adapter is properly connected to power, a green indicator light will be displayed on the adapter.

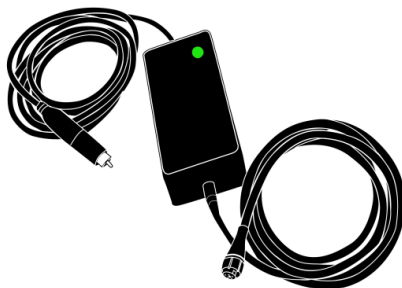


Figure 56: DC adapter

NOTE: The DC adapter is for use in vehicles only and may not fit in some vehicles.

14.1 Connecting the AC Adapter or DC Adapter to the Controller

1. Connect the AC adapter into a grounded electrical outlet or the DC adapter into a power port located in most cars.

WARNING! DO NOT plug the AC adapter into an electrical outlet which is not properly grounded or you may receive a serious electrical shock.

2. Disconnect the battery with the least remaining charge. The corresponding battery indicator will turn off.
3. Grasp the cable of the AC adapter or DC adapter near the connector, leaving the connector free to rotate.
4. Line up the solid white arrow on the connector with the white dot on the controller (Figure 57).



Figure 57: Correct adapter alignment



Figure 58: Correct locking position

5. Gently push the cable into the controller. DO NOT twist the connector, but allow it to naturally lock in place. A successful connection will result in an audible click (Figure 58).

NOTE: When pushing the connector onto the controller, the white arrow will shift slightly. Correct locking position: white arrow aligned with white dot on controller.

6. Confirm that the power cables are properly locked on the controller by gently pulling the cable near the controller power connector.

CAUTION: DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.

CAUTION: ALWAYS confirm that the power cables are properly locked on the controller by gently pulling the cable near the controller power connector or the power cables may come loose and result in an alarm or the pump stopping.

7. Proper connection is also verified when the AC/DC Indicator on the controller turns green and the corresponding power supply indicator illuminates. If the AC/DC Indicator does not turn green, the controller is using battery power only and a “Power Disconnect” alarm will sound.

14.2 Disconnecting from the AC Adapter or DC Adapter

Before switching from AC or DC power to battery power, make sure that a fully charged battery is available. Connect the fully charged battery after disconnecting the AC or DC adapter. To disconnect power cables from the controller:

1. Turn the connector counterclockwise until it stops.
2. Pull the connector straight out from the controller.
3. Connect a fully charged battery to the controller power connector.
4. If a charged battery is not connected to the controller within 20 seconds, the “Power Disconnect” message will be displayed on the controller display and an alarm will sound.

15.0 ALARMS

Visual and auditory alarms tell clinicians and patients about the pump, controller, connections, and power supplies (batteries, AC adapter, DC adapter). A quick reference guide for alarms is located in Appendix A. Alarm conditions are classified as high, medium or low. Each of these alarms has a 1) unique sound, 2) visual display (flashing RED, flashing YELLOW or YELLOW) and 3) message.


When an alarm occurs, two lines of text appear in the controller display. The first line describes the alarm and the second line tells you what to do. When an alarm is resolved, there is no longer an alarm sound or a light displayed in the Alarm Indicator.

WARNING! ALWAYS check the controller display for any information regarding an alarm when using loud machinery or in the vicinity of loud noises as the alarms may not be audible.

WARNING! ALWAYS replace a controller with a blank display or no audible alarms. This condition is predictive of a controller failure.

15.1 High Alarms

A high alarm is the highest priority and loudest alarm; the Alarm Indicator on the controller is flashing RED and the text message demands immediate action for VAD stoppage, controller malfunction or limited power to run the pump. The monitor will also display alarm information.

High Alarms on Controller – Immediate Action Required				
Message on Controller (line 1)	Message on Controller (line 2)	Meaning	Alarm Indicator 	Alarm Sound
(no message)*	(no message)*	Both power supplies removed - VAD stopped	None*	Continuous
VAD Stopped	Connect Driveline	Driveline disconnected or connector malfunction/broken	Flashing RED	Loud Unable to mute alarm
VAD Stopped	Change Controller	Controller failure		
Controller Failed	Change Controller	Controller failure		
Critical Battery 1	Replace Battery 1	Limited battery 1 and battery 2 time remaining		
Critical Battery 2	Replace Battery 2	Limited battery 2 and battery 1 time remaining		

The following are High-Priority Alarms:

***No Power** (no message): If both power sources are disconnected from the controller, a loud, continuous alarm will sound and there will be NO message on the controller display. The HVAD® Pump

is NOT pumping and **power sources should be connected immediately**. If this action does not resolve the alarm condition, replace the controller.

VAD Stopped: The HVAD® Pump will stop if the driveline is disconnected or if the controller fails. The text message indicates whether to connect the driveline or change the controller.

Controller Failed: Indicates a potential controller failure and the controller should be exchanged for a new controller. The HVAD® Pump may not be pumping.

WARNING! ALWAYS switch to the backup controller if there is a “Controller Failed” alarm since the HVAD® Pump may not be running.

Critical Battery: Displayed when there are a few minutes of battery time remaining to power the HVAD® Pump or when the battery has malfunctioned. Replace battery 1 or 2 with a fully charged battery or use the AC adapter or DC adapter.

If the controller has lost communication with a battery and the other power port is connected to either a battery with a remaining capacity of 25% or greater or a valid power adapter, the controller shall generate a **Power Disconnect** alarm associated with the non-communicating battery. This alarm condition will clear or activate a different alarm if any of the following conditions occur:


1. Communication with battery is re-established (alarm will clear).
2. The remaining capacity of other battery drops below 25% (critical battery alarm will be triggered).

When the controller has lost communication with a battery and the other power connector is NOT connected to a valid power supply, or is connected to a battery with a remaining capacity of less than 25%, the controller will generate a **Critical Battery** alarm. This alarm condition will clear when any of the following occur:

1. Communication with battery is re-established.
2. The non-communicating battery is disconnected.
3. The other power source is switched to a valid power adapter or to a battery having a remaining capacity of 25% or greater.

15.2 Medium Alarms

A medium alarm starts at a low volume and gets louder over the next minute, unless the Alarm Mute Button is pressed. Pressing the Alarm Mute Button will silence medium and low level alarms for 5 minutes or until an additional alarm occurs. If the Alarm Mute button is not pressed, after 5 minutes the alarm volume is elevated to the level used in high alarms. A medium alarm is indicated by a flashing YELLOW Alarm Indicator, and the text message tells the patient to call medical personnel for instructions to resolve the alarm condition. For information on how to mute an alarm, see section 15.5, How to Silence (Mute) an Alarm.

Medium Alarms				
Message on Controller (line 1)	Message on Controller (line 2)	Meaning	Alarm Indicator 	Alarm Sound
High Watts	Call	A change in the status of the HeartWare® System is detected	Flashing YELLOW	<ul style="list-style-type: none"> • Gradual increase in volume over the first minute if alarm not muted • Alarm gets louder after 5 minutes if alarm not muted • Able to mute alarm for 5 minutes or 1 hour • Electrical Fault (audio) can be permanently disabled • Controller Fault (audio) can be permanently disabled
Electrical Fault				
Low Flow				
Suction				
Controller Fault	Call	Controller malfunction		
Controller Fault	Call ALARMS OFF	<ol style="list-style-type: none"> 1. Controller malfunction 2. Suction detection, low flow alarms disabled 3. High power and VAD disconnected alarms may be disabled 		

The following are Medium-Priority Alarms:

High Watts: This alarm warns of a high power condition in running the HVAD® Pump. The alarm is triggered when the Watts exceed the High Power Alarm threshold (see section 10.4.3). This may occur due to thrombus or other materials (e.g. tissue fragments) in the device.

Electrical Fault: A fault in the continuity of the pump to controller electrical connection triggers this alarm. The fault could be in the HVAD® Pump motor, driveline and connector, or within the controller. The audio portion of this alarm can be permanently disabled via the monitor (see section 10.4.3). When this alarm condition occurs, the HVAD® Pump will be running on a single stator and will consume slightly more power.

Low Flow: The low flow alarm is triggered if average flow drops below the Low Flow Alarm threshold (see section 10.4.3).

Suction: The ventricular suction detection alarm is triggered if the suction algorithm has identified a ventricular suction condition. This may self-clear if the suction is transient.

Controller Fault: The controller contains two microprocessors - one which controls pump function (PMC) and a second which controls user interface functions (UIC) such as controller display and buttons. The controller fault alarm indicates a possible controller malfunction may have occurred, but during this fault the UIC processor still receives a heartbeat message from the PMC indicating the PMC is still functioning and controlling the pump. The controller fault alarm will result in the word “Call” in the controller display, notifying the patient to call the clinician. The clinician should query the patient about the frequency and duration of alarm as well as any additional alarms and changes in pump flow, speed or power. The patient should also be asked about any clinical symptoms/changes including dizziness, shortness of breath, angina and/or palpitations. Based on the patient's responses, the following course of action should be taken:

- If there was a single, isolated controller fault alarm with no change in pump or clinical parameters, instruct the patient to report any additional alarms that may occur. Download the controller log files at the patient's next clinic visit and send to HeartWare for analysis.
- Instruct the patient to return to the center as soon as reasonable (not emergently) so the controller log file can be downloaded and sent to HeartWare for analysis if one of the following situations occurs:
 - If a controller fault alarm has occurred and been resolved multiple times over a 24 hour period, or
 - If a controller fault alarm has occurred in conjunction with other alarms even though it has not affected pump flow, power or speed and there are no concurrent clinical symptoms.

The decision to change the controller or what other action is needed will be based on the log file analysis and the patient's clinical condition.


- The patient should be instructed to change the controller and return to the implanting center as soon as is reasonable (within 12-16 hours) if one of the following occurs:
 - The controller fault alarm is occurring frequently (more than 1 time per hour), with increasing frequency,
 - If the controller fault alarm has occurred and not resolved,
 - If the controller fault alarm has occurred in conjunction with other alarms, and is associated with a change in pump flow, speed or power or any adverse clinical symptom such as light headedness or shortness of breath.
 - Download the log files from the original controller and the current controller and send them to HeartWare for analysis.

When a medium alarm resolves, there is no audible alarm or light displayed in the Alarm Indicator located on the controller. However, the message on the controller display will remain until the message is cleared by pressing the Scroll Button. A new alarm will also clear a resolved medium alarm from the controller display. For instructions on how to silence (mute) an alarm, see section 15.5.

The Controller Display and Alarm Indicator will continue to display all active alarms. Any new alarm condition will inactivate the 60-minute mute. The controller fault alarm audio can be permanently silenced but this cannot be done by the patient (requires the monitor, see Section 10.4.3, Alarm Settings Tab).

15.3 Low Alarms

A low alarm is indicated by a solid YELLOW Alarm Indicator. The message indicates whether to replace a low battery or reconnect a power source (battery, AC adapter or DC adapter). The alarm gets louder after 5 minutes and even louder after 10 minutes, if the alarm is not muted.

Low Alarms on Controller				
Message on controller (line 1)	Message on controller (line 2)	Meaning	Alarm Indicator 	Alarm Sound
Low Battery 1	Replace Battery 1	Battery 1 is low	YELLOW	Alarm gets louder after 5 minutes and even louder after 10 minutes, if alarm not muted. Able to mute alarm for 5 minutes. Press Alarm Mute Button.
Low Battery 2	Replace Battery 2	Battery 2 is low		
Power Disconnect	Reconnect Power 1	Power source 1 is disconnected or defective		
Power Disconnect	Reconnect Power 2	Power source 2 is disconnected or defective		


The following are Low-Priority Alarms:

Low Battery: This alarm is triggered if any batteries have a remaining capacity between 10% and 25%.

Power Disconnect: This alarm is triggered if a controller power source is disconnected or defective. The power supply should be replaced immediately because the patient will be without a backup power source.

WARNING! NEVER disconnect both power sources (batteries and AC or DC adapter) at the same time since this will stop the pump. At least one power source must be connected at all times.

15.4 Multiple Alarms

It is possible to have concurrent alarm conditions. For multiple alarms, the Alarm Indicator  will display the color of the most severe alarm and the alarm will sound the most severe alarm. An arrow is displayed on the right side of the alarm for multiple alarms (Figure 59). Use the Scroll Button to see all active alarms.

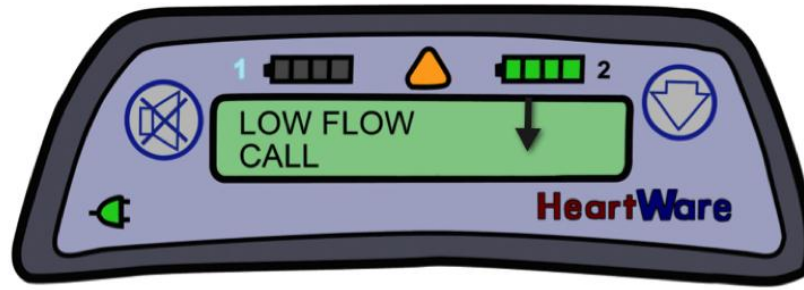



Figure 59: Controller displaying multiple alarms

Alarm Indicator and Alarm Sound for Multiple Alarms		
Multiple Alarm Condition	Alarm Indicator 	Alarm Sound
More than 2 High Alarms	Flashing RED	Loud, continuous, unable to mute
High and Medium Alarm	Flashing RED	Loud, continuous, unable to mute
High and Low Alarm	Flashing RED	Loud, continuous, unable to mute
More than 2 Medium Alarms	Flashing YELLOW	Gradual increase in volume if alarm NOT muted
Medium and Low Alarm	Flashing YELLOW	Gradual increase in volume if alarm NOT muted
More than 2 Low Alarms	YELLOW	Gradual increase in volume if alarm NOT muted
NOTE: If an arrow is displayed on the right side of the alarm message, there are multiple active alarms. Use the Scroll Button to see all alarm conditions. Press the Scroll Button to advance to the next alarm or to the pump parameters (flow, speed and power). If the Scroll Button is not touched for 1 minute, the controller automatically displays the most severe alarm on the controller display. If a new alarm occurs, the controller display will show the new alarm.		

15.5 How to Silence (Mute) Alarms

High alarms CANNOT be silenced. However, medium and low alarms may be silenced for 5 minutes by pressing the Alarm Mute Button.

Clinicians can also mute medium alarms for one hour by pressing and holding the Alarm Mute Button, then pressing and holding the Scroll Button, followed by releasing the Alarm Mute Button, and finally releasing the Scroll Button.

The alarm will sound again if a new alarm condition occurs during the mute interval. The medium priority “Electrical Fault” alarm and “Controller Fault” alarm can be permanently disabled by accessing the Alarm Settings in the monitor’s System Screen (see Section 10.4.3).

WARNING! ALWAYS investigate, and if possible, correct the cause of any alarm. Silencing an alarm does not resolve the alarm condition.

15.6 Status Message Display

The monitor may display a status message where alarms are typically displayed. The following are potential status messages:

Message	Potential Causes
VAD Off	Driveline connected to controller and HVAD® Pump manually stopped
Data @ Limit	Patient data cannot be stored due to maximum number of patients or lack of storage space

NOTE: The monitor will overwrite files at its data limit which is based on the amount of hard disc space used. The USB flash drive can be used to transfer log files.

16.0 SURGICAL IMPLANT PROCEDURE

NOTE: In order to optimize patient outcomes HeartWare suggests that the following techniques be considered at the time of HVAD® Pump implant:

- TEE
 - Inspect LA and LV for thrombus – thoroughly remove any thrombus present
 - Check for PFO – PFO should be surgically repaired prior to HVAD® Pump implant
- Coring
 - After coring, make sure margins of the core are clean and smooth
 - Perform visual inspection of cored area and remove any loose tissue and/or clots
- De-Airing
 - After placement of HVAD® Pump in the LV, passively fill the LV and pump.
 - Elevate the apex of the heart and shake gently to remove any entrapped air in the heart/HVAD® Pump.
 - Clamp the distal outflow graft. After anastomosis of the outflow graft to the ascending aorta, complete the de-airing process using standard technique.
- Pump Speed (RPM)
 - Prior to starting the HVAD® Pump, the LV should be full. The pump must always start at 1800 RPM.
 - Speed should be increased by no more than 100 RPM at a time.
 - Increase the HVAD® Pump speed slowly to avoid suction events. Suction events can lead to the ingestion of tissue/clot from inside the LV, and may also lead to episodes of ectopy.

16.1 HeartWare® Ventricular Assist System Setup

WARNING! The HVAD® Pump may cause interference with AICDs. If electromagnetic interference occurs it may lead to inappropriate shocks arrhythmia and possibly death. The occurrence of electromagnetic interference with AICD sensing may require adjustment of lead sensitivity proximal placement of new leads or replacement of an existing sensing lead.

CAUTION: DO NOT use HeartWare equipment in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Battery Charger

1. Connect the battery charger power cable to an electrical outlet. Verify the power indicator is lit next to “HeartWare.”
2. Verify availability of four fully charged batteries. If batteries are not fully charged, start charging depleted batteries at least 4 hours before the HVAD® Pump implant procedure.

Monitor

1. Connect the monitor power cord to an electrical outlet.
2. Turn the monitor on. The monitor program will appear in a few minutes.
3. Connect the monitor data cable to the serial port on the monitor and to the blue connector on the controller.
4. Press the HVAD® Pump Icon to access the System Screen and enter the password (see section 10.4 for more detail).
5. Press Setup tab to display Patient, VAD, Controller, and Monitor tabs (see section 10.4.2).
6. Press the Monitor tab and enter monitor date and time.

Backup Controller

1. Press the Controller tab on the Setup Screen, and then press the ‘Disable “VAD Stop” Alarm’ button.
2. Connect the monitor data cable to the blue data port on the controller.
3. Plug the AC adapter into an electrical outlet.
4. Connect the controller to the AC adapter.
5. Connect a fully charged battery to the controller.

NOTE: Once powered, the controller performs a self-test and will display a temporary message regarding the status of the self-test. If the controller fails the self-test, a controller fault alarm message will appear. In that case replace the controller with the second controller.

6. Press Speed/Control tab and reduce the set speed to 1800 RPM.

7. Press Setup tab to display Patient, VAD, Controller, and Monitor tabs (see Section 10.4.2 “Setup Tab”).
8. Press the Patient tab and enter the Patient ID and Implant Date.
9. Ensure the Hematocrit setting is 30%.
10. Press VAD tab and enter HVAD® pump serial number and verify that Suction Response is “Off”.
11. Press Controller tab and enter controller date and time.
12. Press the Alarm Settings tab to set the Low Flow Alarm limit and High Power Alarm limits. Default settings are 1 L/min for low flow and 16 watts for high power.
13. Remove data cable.
14. To prevent the controller alarm from sounding after the power is removed, follow these instructions:
 - If a red alarm adapter is available: Insert it into the blue connector on the controller.
 - If no alarm adapter is available: Press and hold the Alarm Mute and Scroll Buttons on the controller until a “beep” is heard, or for at least 5 seconds.
15. Disconnect both power sources from controller.
16. Set the backup controller aside for use during the Pre-Implant Test.

CAUTION: A backup controller should always be available and programmed identically to the primary controller.

Programming Initial Settings for the Primary Controller

1. Press the Controller tab on the Monitor Setup Screen, and then press the ‘Disable “VAD Stop” Alarm’ button.
2. Connect the monitor data cable to the blue data port on the controller.
3. Plug the AC adapter into an electrical outlet.
4. Connect the primary controller to the AC adapter.
5. Connect a fully charged battery to the controller.
6. Press Speed/Control tab and reduce the set speed to 1800 RPM.
7. Press Setup tab to display Patient, VAD, Controller, and Monitor tabs (see Section 10.4.2 “Setup Tab”).
8. Press the Patient tab and enter the Patient ID and Implant Date.
9. Ensure the Hematocrit setting is 30%.
10. Press VAD tab and enter HVAD® Pump serial number and verify that Suction Response is “Off”.
11. Press Controller tab and enter controller date and time.
12. Press the Alarm Settings tab to set the Low Flow Alarm limit and High Power Alarm limits. Default settings are 1 L/min for low flow and 16 watts for high power.

13. Press the Logout button and return to the Clinical (Home) Screen
14. After setting up the primary controller, keep both power supplies connected to the controller so that the pump does not stop, then restart automatically when power is restored. During implant the HVAD® Pump should be started only by pushing the password-protected “Start” button.
15. Place the controller in the Patient Pack (carry bag) and position the bag close to the head of the OR table so the driveline can be connected to the controller after tunneling.

WARNING! Keep both power supplies connected to the controller after setting up the primary controller to minimize the risk of air embolus during implant. Disconnecting and then reconnecting both power supplies will result in the controller starting the pump as soon as the driveline is connected.

NOTE: Any changes to the primary controller should also be made to the backup controller.

16.2 HVAD® Pump Pre-implant Test

1. Examine the HVAD® Pump implant kit package and other component packaging. They must be unopened and without any visible damage including abrasion, delamination or punctures.

WARNING! DO NOT use if package is damaged or opened. Sterile components are intended for single use only. DO NOT re-sterilize or re-use as this will increase the risk of infection.

2. Set up a sterile back table to prepare and test the HVAD® Pump.
3. Open the driveline extension cable first. Pass it onto the sterile field, wipe it off with a damp sponge and set on sterile back table. Dispose of sponge and change gloves.

NOTE: The driveline extension cable should only be used during the pre-implant test. It should not be connected when the VAD is running.

4. Grasp the Tyvek lid of the HVAD® Pump implant kit package at the point indicated and peel back, taking care not to contaminate the inner sterile tray.
5. Pass the HVAD® Pump tray and other components aseptically onto the sterile field. Examine all components, including the surgical tools, for damage, corrosion or any abnormalities that might affect the safety or functionality of the tools. If any abnormalities are noted please use the appropriate backup supplies.
6. Cover the HVAD® Pump with a sterile towel. With the driveline extended on the back table, remove the Tyvek sleeve (peel off by hand) covering the polyester covered portion of the driveline (see Figure 60). Wipe the driveline with a lap sponge moistened with antibiotic irrigation and discard the sponge.

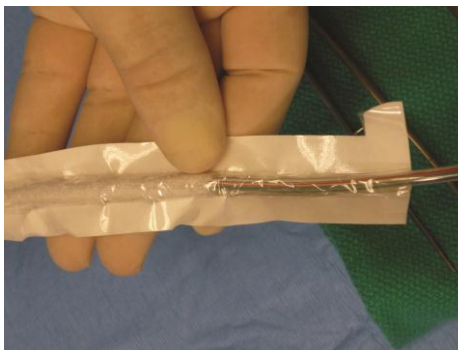


Figure 60: Tyvek sleeve covering polyester on driveline

7. On the sterile field, fill a basin with 2 liters of 5% dextrose.
8. Attach the sterile driveline extension cable to the HVAD® Pump and pass the distal portion of the cable (labeled “Controller”) to the non-sterile assistant.

WARNING! ALWAYS check for an audible click when connecting the driveline to the controller or driveline extension cable. Failure to ensure a secure connection may cause an electrical fault.

9. Clamp the sterile portion of the extension cable to the sterile field on the table to prevent cable movement.
10. The non-sterile assistant should have the backup controller and a charged battery ready for use. Completely submerge the HVAD® Pump in the dextrose solution. Fill the pump with dextrose and gently rotate it with the inflow cannula facing up in the dextrose to allow any trapped air to escape.
11. At least 4 inches (10.2 cm) of dextrose solution must be above the VAD inflow and outflow conduits.
12. When the HVAD® Pump is completely submerged in the sterile basin and is de-aired, point the inflow cannula towards the wall of the basin and position your hand over the VAD outflow.
13. The non-sterile assistant should connect the driveline extension cable to the controller, and then connect the battery to the controller. Ensure that the driveline extension cable boot is pushed fully forward to cover the exposed metal driveline connector and the mating connector on the controller.
14. The pump will start at 1800 RPM.

WARNING! NEVER turn on the HVAD® Pump in air as this may damage the pump. DO NOT use an HVAD® Pump that was turned on without total submersion in fluid during the pre-implant test and prior to implantation: The HVAD® Pump must be completely submerged in fluid before being turned on.

NOTE: During the HVAD® Pump Pre Implant Test, a low priority alarm will sound since one of the controller power ports is empty.

15. Run the pump for 30-60 seconds. **If, at any time during this test, the power exceeds 3 Watts, do not use the pump - set it aside and repeat this process using the backup HVAD® Pump.**

16. After the test is complete, disable the “no power” alarm. If a red alarm adapter is available, insert it into the blue connector on the backup controller. If no alarm adapter is available, press and hold the Alarm Mute and Scroll Buttons until a “beep” is heard, or for at least 5 seconds. Remove the battery from the controller. This will power down the controller and will stop the pump.
17. Wearing clean, dry gloves disconnect the driveline extension cable from the controller and the HVAD® Pump.
18. Connect the driveline cap to the driveline by pushing both connectors together until you feel a “click” (Figure 61). Protect the connector from exposure to fluids.

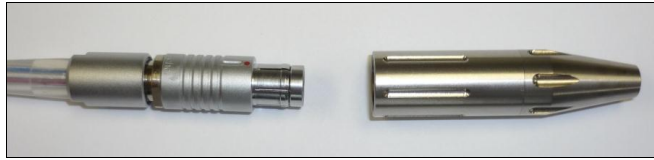


Figure 61: Driveline cap connection

19. Cover the inflow cannula of the HVAD® Pump with the yellow inflow cap.

16.3 Outflow Graft Attachment

1. Examine the outflow graft package. It must be unopened and without visible damage.

WARNING! DO NOT implant gel impregnated vascular prostheses in patients who exhibit sensitivity to polyester or materials of bovine origin, as severe reactions may occur.

2. Open the package aseptically, taking care not to contaminate the sterile graft.

WARNING! DO NOT allow the Gelweave prostheses non-sterile foil pouch or outer tray to be introduced to the sterile field or the sterile field will be contaminated. Only the innermost tray is sterile.

WARNING! DO NOT preclot the outflow graft. Preclotting may disrupt the gel matrix, resulting in bleeding. Gelweave prostheses are sealed grafts and must not be preclotted.

WARNING! DO NOT implant the Gelweave prostheses more than one month after removal from the foil pouch. This may disrupt the gel matrix, resulting in bleeding.

3. Pass the outflow graft onto the sterile field.

WARNING! DO NOT allow anyone but a surgeon, physician’s assistant or surgical assistant trained in the procedure to attach the outflow graft to the pump, as a loose graft connection may lead to bleeding and/or an air embolus.

4. Slide the strain relief over the outflow graft (Figure 62). Next, stretch the outflow graft over the HVAD® Pump outflow conduit (Figure 63). Hemostats can be used to assist with the procedure. Verify that the outflow graft is not kinked or twisted. If necessary, reattach graft if kinking or twisting occurs.

CAUTION: DO NOT exert excessive tension or force on the Gelweave prostheses as it will damage the polyester fibers and the gelatin impregnation, which may result in bleeding.



Figure 62: Strain relief over outflow graft



Figure 63: Stretch outflow graft over pump outflow conduit

5. Loosen the graft clamp screw and place the graft clamp over the lip of the HVAD® Pump outflow conduit. Verify that the clamp screw is on the outflow conduit and attached to the graft clamp.
6. Tighten the clamp screw slightly with the hex driver, then rotate the strain relief so that clamp screw is located on the inner side of the outflow conduit (Figure 64). Finish tightening the clamp screw until resistance is met.



Figure 64: Rotate clamp screw to inner side of outflow conduit

WARNING! ALWAYS rotate the strain relief so that the clamp screw is located on the inner side of the outflow conduit to avoid tissue irritation or damage.

WARNING! DO NOT use excessive force when tightening the clamp screw because this could damage the graft clamp or graft clamp screw and a loose connection may result in bleeding and/or an air embolus. Replace components if required.

7. Gently pull on the outflow graft to verify secure placement of the graft clamp to the outflow conduit.
8. Inspect the outflow graft and strain relief for any kinks or twisting. Reattach the outflow graft if necessary.
9. Clamp the HVAD® Pump outflow graft with a vascular clamp, then wrap it all in a clean towel.

16.4 Pump Implantation Preparation

1. Make a standard median sternotomy incision.
2. Open the pericardium to expose and access the left ventricle (LV) apex.
3. Consider a transesophageal echocardiography (TEE) prior to placing the patient on cardiopulmonary bypass to assess for a patent foramen ovale (PFO). If present, correct the defect prior to HVAD® Pump implantation.
4. Consider flooding the field with CO₂ when appropriate to reduce residual intracardiac air during surgery.

16.5 Left Ventricle (LV) Apex Cannulation

1. Elevate the LV apex.
2. Select the insertion site for the HVAD® Pump inflow cannula. It should be anterior to the LV apex with the inflow cannula pointing to the mitral valve and parallel to the interventricular septum. Evaluate where the HVAD® Pump will sit when implanted. If it appears it will directly contact adjacent rigid structures, such as the chest wall, consider placing the pump on the diaphragmatic surface, opening the left pleural space, or wrapping it in a sheet of PTFE.

CAUTION: ALWAYS ensure the inflow cannula position is pointed toward the mitral valve and parallel to the interventricular septum to optimize HVAD® Pump operation.

3. Attach the sewing ring to the myocardium using 8-12 pledgeted, double-armed polypropylene sutures. Use felt strips or a felt ring for reinforcement if necessary.

CAUTION: ALWAYS position the sewing ring to permit access to its screw after cannulation.

4. Perform a full-thickness cruciate incision inside the sewing ring using an 11-blade scalpel.
5. Using the apical coring tool (Figure 65), create and remove the apical core. To use the apical coring tool:
 - Insert the thumb in the thumb ring and wrap the first two fingers around the handle. Push the ring forward with your thumb, extending the cutting head.
 - After the cutting head is completely extended, place the cutting head through the myocardium. Release tension.
 - Grasp the tool with one hand and use the other to rotate the cutting head as it retracts.

- Cored tissue is captured within the cutting head.



Figure 65: Apical coring tool

6. Perform a visual inspection of the left ventricle and remove any thrombus or potential obstruction to the inflow cannula.
7. Place a clamp on the HVAD® Pump outflow graft.
8. Remove the inflow cap from the HVAD® Pump inflow cannula and keep the HVAD® Pump outflow graft cross-clamped.
9. Insert the inflow cannula into the ventricle. Ensure that the HVAD® Pump housing is flush with the sewing ring housing.
10. Use the sewing ring wrench (Figure 66) to tighten the sewing ring's screw around the HVAD® Pump inflow conduit. Use the wrench to tighten the screw until an audible "click" is heard.

WARNING! DO NOT over-loosen the sewing ring's screw or it may fall off the sewing ring and be lost in the sterile field.

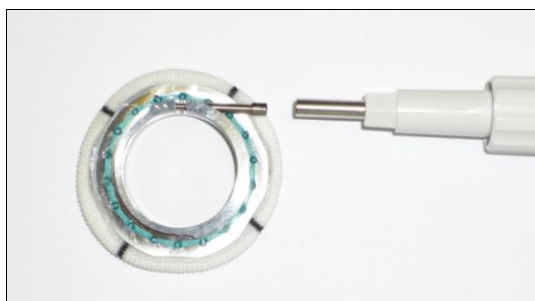


Figure 66: Sewing ring wrench

11. Verify no blood or air leakage around the sewing ring. Add reinforced pledgeted sutures as needed.

16.6 Outflow Graft Anastomosis

1. Gently stretch the outflow graft, measure and cut to length. The outflow graft should lie without kinking or overstretching.
2. Place a partial occlusion clamp on the portion of the ascending aorta where the outflow graft will be placed.
3. Make a longitudinal arteriotomy and sew the outflow graft to the aorta with 4-0 or 5-0 polypropylene (or similar material) sutures.

4. Remove the partial occlusion clamp from the aorta and ensure an intact anastomosis without bleeding, while keeping the HVAD® Pump outflow graft clamped.

WARNING! DO NOT cut the outflow graft too short or too long, or it may kink. Prior to chest closure, ensure that the graft is not kinked or compressed. A kinked or compressed outflow graft may lead to reduced flow and/or thrombus formation.

WARNING! DO NOT immerse the Gelweave grafts in saline for longer than 5 minutes. Longer periods of soaking in saline may disrupt the gel matrix, resulting in bleeding.

CAUTION: ALWAYS use round body taper point needles when implanting Gelweave prostheses to minimize fiber damage. A kinked or compressed outflow graft may lead to reduced flow and/or thrombus formation.

16.7 Driveline Placement

Select the location where the driveline will exit the skin. Consider the position of major organs and structures when determining the path of the tunneler. Massage antibiotic solution into the external surface of the driveline's woven polyester velour.



Figure 67: Tunneler

The tunneler (Figure 67) is designed so that the handle can be attached and detached. To attach the handle to the tunneling rod, depress the locking pin, insert the tunneling rod into the handle until it bottoms out, release the locking pin and rotate the handle until the locking pops out. Using the tunneler, tunnel the driveline lead to the point of exit. Adjust distance of exit site from costal margin to fit body habitus and prevent rubbing against the costal margin.

WARNING! ALWAYS position the driveline exit site so that the tunneler does not contact any vital organs or structures.

CAUTION: The driveline connector is made of nickel-coated brass which may cause a rash in patients with a nickel allergy.

CAUTION: ALWAYS be aware of the position of the driveline to avoid damage by surgical instruments and needles during HVAD® Pump implantation and/or re-operation.

Once the tunneling path has been made, screw the driveline cap on to the tunneling rod tip, as shown in Figure 68. Pull the driveline through the tunneling path once it is secured to the tunneling tool.



Figure 68: Driveline cap attachment to tunneler

NOTE: Failure to follow instructions on protecting the driveline connector or improper use of the driveline cap could result in contamination or damage to the connector and electrical fault alarms could occur.

Disconnect the tunneling rod from the driveline cap. Do not remove the driveline cap until it is time to connect the driveline to the controller. Make sure to protect the driveline connector from contamination during this time. Prior to removing the driveline cap, put on clean, dry gloves. To remove the driveline cap, unscrew the outer sleeve and pull back on the grooved part of the connector. Next, place the white, rubber driveline cover over the driveline connector. Verify that the connector is dry and clean before attaching to the controller. If the driveline connector contains any fluid, tissue or foreign material, thoroughly clean it with isopropyl alcohol and dry it with a clean cloth. Attach the driveline to the controller and slide the driveline cover forward to completely cover the controller's silver driveline connector. After the driveline is connected to the controller, the driveline cover is on, and the pump has started, immobilize the driveline at the exit site with retaining sutures.

WARNING! DO NOT grasp the driveline and pull as this may damage the driveline. To remove the driveline cap from the driveline, unscrew the outer sleeve, then pull back on the grooved part of the connector.

16.8 De-airing Procedure

1. Start ventilation.
2. Be sure that all IV catheters and pressure monitoring lines are closed to the atmosphere to reduce the possibility of air entering the heart and pump.
3. Reduce cardiopulmonary bypass flow to allow filling of the left ventricle and pump.
4. Place a sterile 19-gauge needle into the outflow graft between the HVAD® Pump and the outflow graft clamp.

CAUTION: Always use the smallest possible needle for de-airing; 19-gauge is normally sufficient. Hypodermic needles have a cutting point which may result in blood leakage and may require repair by suturing.

5. Start HVAD® Pump at 1800 RPM by pressing the blue button labeled "START" on the monitor.
6. With the HVAD® Pump at 1800 RPM, use TEE to assess air in the left ventricle and aorta.

WARNING! ALWAYS remove all air from the HVAD® Pump and its conduits to reduce risk of air embolus.

WARNING! DO NOT de-air the HVAD® Pump when there is inadequate blood volume in the HVAD® Pump or leaks in the inflow/outflow connections, as air may enter the HVAD® Pump and outflow graft resulting in a delay in de-airing and possible air embolism.

CAUTION: DO NOT rely on HVAD® Pump flow estimation during the de-airing procedure. Flow estimation may not be accurate.

7. After all air is removed, remove the 19-gauge needle and oversew the needle hole with pledgeted sutures.
8. Release the outflow graft cross clamp.
9. Gradually increase HVAD® Pump speed to achieve the desired flow and wean from cardiopulmonary bypass as tolerated.

NOTE: Increase HVAD® Pump speed in increments of 100 RPM with a 20-second interval between speed changes to gradually increase flow and to help prevent ventricular collapse.

16.9 Programming the Backup Controller to Match the Primary Controller

A backup controller should always be available and programmed identical to the primary controller. The backup controller should be programmed before the implant procedure, prior to patient transfer from the operating room, when the primary controller is replaced, and upon any parameter change to the primary controller.

Parameters include:

1. Pump speed
2. Hematocrit setting
3. VAD ID/Pump serial number
4. Suction Response setting
5. Controller date and time
6. Low Flow Alarm limit
7. High Power Alarm limit
8. Patient ID

See section 16.1 for instructions on programming the controller and removing power from the backup controller.

17.0 HVAD® PUMP EXPLANT

17.1 At Transplant

1. Surgically expose the HVAD® Pump and sewing ring.
2. Place patient on cardiopulmonary bypass according to institutional guidelines.
3. Connect the controller to the monitor and turn off the HVAD® Pump.
4. Cross-clamp two (2) sections of the outflow graft.
5. Cut outflow graft between two (2) clamps.
6. Cut and remove the percutaneous driveline.
7. Remove the HVAD® Pump with the heart.

17.2 Myocardial Recovery/ Pump Exchange

1. Surgically expose the HVAD® Pump and sewing ring.
2. Place patient on cardiopulmonary bypass according to institutional guidelines.
3. Connect the controller to the monitor and turn off the HVAD® Pump.
4. Cross-clamp two (2) sections of the outflow graft.
5. Cut outflow graft between two (2) clamps.
6. Cut and remove the percutaneous driveline.
7. Excise the remaining outflow graft from the aorta and repair the arteriotomy site.
8. Use the sewing ring wrench to loosen the sewing ring screw.
9. Remove the HVAD® Pump.
10. For pump exchange, refer to section 16.5, LV Apex Cannulation (starting at step #6). For myocardial recovery, follow the steps below.
11. Repair the hole in the LV.
12. Close sternum and skin incision per routine.
13. Once HVAD® Pump is explanted, rinse gently with NaCL.
14. Place HVAD® Pump in 5% Formaldehyde for at least 2 days.
15. Allow the HVAD® Pump to thoroughly dry.
16. Follow the packaging instructions provided in the Explant Kit (provided by HeartWare) and return the HVAD® Pump in the Explant Kit.

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18.0 PATIENT MANAGEMENT

18.1 Postoperative Management

After implantation, the patient is returned to the intensive care unit. Fluids are given to maintain pump flow index (pump flow ÷ BSA) at greater than 2.0 L/min/m² with central venous pressure and left atrial pressure less than 20 mmHg. Some vasopressor and/or vasodilatory pharmacologic assistance can be used as required to adjust vasomotor tone. Patients may require inotropic assistance to improve right ventricular function.

WARNING! To mitigate the risk of stroke, please adhere to the following patient management guidelines:

- Maintain MAP at <85 mm Hg as tolerated. The HVAD® Pump is sensitive to both preload and afterload.
- Ramp speed and flows more slowly during the first few weeks (e.g. 30 days) post-implant to avoid excessive hemodynamic forces that may damage fragile blood vessels that have undergone remodeling secondary to the lower pressures and reduced flow associated with medically-treated heart failure. There is no apparent need to exceed a cardiac index of 2.6 L/min/m² until patients have fully recovered from the implant surgery and physical performance improves. A cardiac index of 2.6 L/min/m² is the lower limit of normal for a healthy adult.
- Maintain anticoagulation within the recommended INR range of 2.0-3.0.
- Check for ASA resistance with a reliable test (e.g. VerifyNow®) and adjust ASA mono-therapy accordingly or consider combination therapy such as ASA 81 mg plus Aggrenox® (ASA plus extended-release dipyridamole) or daily ASA 81 mg plus Plavix 75 mg. In general, mono-therapy with ASA is not encouraged in the absence of testing for resistance.

NOTE: Recommended HVAD® Pump speeds are between 2400 RPM and 3200 RPM. HVAD® Pump speeds outside this range may result in less than optimal HVAD® Pump operation.

NOTE: HVAD® Pump speed should be adjusted according to a calculated cardiac index. During the first few weeks post-implant, excessive hemodynamic forces may damage fragile blood vessels that have undergone remodeling secondary to the lower pressures and reduced flow associated with medically-treated heart failure. Unless there is a clear clinical need for higher flows, the cardiac index should be set at 2.6-2.8 L/min/m² until patients have fully recovered from the implant surgery (2-3 months) and/or physical activities require higher levels of support.

18.2 Emergency Management

In the event of an emergency, such as a cardiac arrest, patients with the HeartWare® System may be defibrillated with either an internal or external defibrillator. The HeartWare® System can be left on, nothing needs to be turned off or disconnected. If chest compressions are performed, confirm function and positioning of HVAD® Pump once the patient is stable.

CAUTION: Chest compressions may pose a risk due to pump location and position of the outflow graft on the aorta - use clinical judgment. If chest compressions have been administered, confirm function and positioning of HVAD® Pump.

18.3 Anticoagulation

Prior to HVAD® Pump implantation, many patients with refractory heart failure have abnormal coagulation due to abnormal liver function and chronic use of anticoagulation. Prolonged INR can be associated with significant postoperative bleeding. The INR, PTT, and platelet count should be performed prior to HVAD® Pump implantation. The return of each of these parameters to a normal range prior to HVAD® Pump implantation is an important goal.

Anticoagulation should be individualized for each patient. In general, begin low-dose heparin at 10 units/kg/hr on postoperative day one to a target PTT of 40-50 seconds. Prior to initiation of anticoagulation, chest tube drainage should be less than 40 ml/hr for approximately three hours; the HCT should be stable without the need for transfusion of blood products, and coagulation factors approaching normal. Gradually increase the heparin dosage to maintain the aPTT in a range of 50-60 seconds.

The recommended long term oral anticoagulation regimen for the HVAD® Pump is a combination of warfarin and aspirin. In general, aspirin should be started at a dose such as 325 mg/day within 24 hours after implant if there are no postoperative bleeding complications. However, if ASA alone is the medication chosen for anti-platelet therapy, a check for ASA resistance with a reliable test (e.g., VerifyNow®) is recommended to establish the dose or to select an alternative medication. Multi-drug options include:

- ASA 81 mg plus Aggrenox® (ASA (25 mg) plus extended –release dipyridamole (200 mg))
- ASA 81 mg plus clopidogrel 75 mg daily

For patients who are aspirin sensitive or otherwise intolerant, clopidogrel at doses of 75-150 mg/day is a viable alternative. A clopidogrel loading dose of 300 mg followed by 75 mg/day is recommended to reduce the lag time in reaching full therapeutic benefit (typically a 3-4 day lag). Warfarin should be started within 4 days post-op and titrated to maintain an INR of 2.0 to 3.0.

18.4 Infection Control Guidelines*

For prevention of infection, remove unnecessary IV lines and replace old IV lines before HVAD® Pump implantation. Administer antimicrobial prophylaxis based on the hospital's nosocomial and microbial sensitivity profile with sufficient coverage for staph aureus, staph epidermidis and enterococcus. Use pre-operative scrub with antiseptic the night before and again the morning of the operation. After HVAD® Pump implantation, continue systemic antimicrobials prophylaxis for 48 to 72 hours. Remove mediastinal and pleural drains as soon as appropriate. Early extubation, removal of monitoring lines, and patient ambulation are encouraged. Rapid restoration of oral nutrition should be attempted using tube feeding if necessary. Turning the patient side to side can start once the patient is clinically stable. Physical therapy and active range of motion can begin on the first postoperative day. The patient can be moved to a chair and can/should use an exercise bicycle or treadmill as soon as possible. Nursing measures to decrease infection include frequent hand washing and strict aseptic technique during contact with invasive lines and during HVAD® Pump dressing changes.

18.5 Driveline Care*

To minimize the risk of infection, driveline exit site dressings should routinely be changed. Routine driveline/exit site care is the responsibility of the patient and the primary caregiver. For proper HVAD® Pump driveline and exit site care, please ensure the following:

1. Use good hand-washing technique before and after dressing changes.
2. Always use aseptic technique.
3. Change dressings per institutional protocol/guidelines.
4. Once the exit site dressing is removed, the driveline should be visually inspected for kinks, tears or other damage. If blood is seen within the lumen of the driveline, the implanting center should be notified immediately.

*Infection Control Guidelines and Driveline Care based on recommendations from “Multicenter Experience: Prevention and Management of Left Ventricular Assist Device Infections”. Chinn et al. ASAIO Journal 2005; 51:461–470

CAUTION: ALWAYS examine the driveline for evidence of tears, punctures or breakdown of any of the material during exit site dressing changes. Driveline damage may affect HeartWare® System performance.

5. Perform exit site care every 24-48 hours using an antiseptic cleansing agent, such as a diluted chlorhexidine scrub solution. Following aseptic cleansing, rinse and dry the site to avoid tissue injury. Aseptic technique should be followed anytime the dressing is removed and the exit site is exposed, inspected, dressed or handled. When performing exit site care, be sure to wear a cap, mask and sterile gloves.

CAUTION: AVOID the use of prophylactic topical antibiotic ointments such as silver sulfadiazine, betadine or polymyxin-neomycin-bacitracin on the tissue around the driveline exit site as these ointments can injure the tissue.

6. Immobilize the percutaneous lead with occlusive dressing and if necessary, a Hollister clip, Montgomery strap, or a custom-made percutaneous lead immobilization binder or belt. Keep the extra external length of the driveline under a binder or clothing.
7. Complicated, non-routine driveline dressing changes that involve exit site infections may require assistance/supervision from a health care professional.
8. For wounds/incisions other than the driveline exit site that require dressing changes and/or other care, the ability of the patient and caregiver to provide that care will be evaluated by the implanting center. Treatment plans will be dependent upon this evaluation.

18.6 Arrhythmias

The HVAD® Pump functions most effectively when adequate and stable amounts of preload are available. A stable supraventricular rhythm helps to optimize right heart performance and provide the HVAD® Pump with preload. Many heart failure patients will have permanent pacemakers and internal defibrillators in place by the time an LVAD is implanted. These devices are often needed in the early postoperative period.

18.7 Right Heart Failure

Right heart failure is common in patients receiving LVADs. Right heart failure usually develops within the first 24 hours after LVAD implant. Warning signs include increasing right atrial pressure (RAP) with concurrent decreases in the pulmonary capillary wedge pressure (PCWP) and LVAD flow. Systemic hypotension, tachycardia and a decrease in urine output soon follow. Volume should be given to increase the RAP to 15-18mmHg. This can be accomplished quickly and easily in the operating room while the patient is on cardiopulmonary bypass. Increasing the RAP to >20mmHg is usually ineffective. After optimizing intravascular volume, increasing inotropic drug support in conjunction with pulmonary vasodilators such as nitric oxide is usually effective. If volume and pharmacological therapy fail, a right ventricular assist device (RVAD) should be considered. Late right heart failure (weeks to months) post LVAD implant is unusual but would manifest itself with similar but less acute symptoms. The etiology of late right heart failure may be a progression of chronic heart disease such as coronary artery disease and/or right ventricular infarction. The cause of the right heart dysfunction should be identified and treated appropriately.

18.8 Blood Pressure Maintenance

The restoration of normal perfusion may lead to systemic hypertension in susceptible patients. Since the HVAD® Pump provides continuous flow, resulting in narrow arterial systolic/diastolic pulse pressures, it is best to monitor the mean arterial pressure (MAP). MAP should be monitored and maintained at <85 mmHg. The blood pressure should be manually auscultated; however, it may be necessary to use a Doppler probe. If unable to manually auscultate a blood pressure or use a Doppler probe or if hypotension precludes either method, consider placing an arterial line.

18.9 Physical Rehabilitation

Physical Rehabilitation begins as soon as the patient admitted to the intensive care unit is stable. Early extubation, removal of monitoring lines, and patient ambulation are encouraged. Turning the patient from side to side should start once the patient is clinically stable. Physical therapy and active range of motion may begin on the first postoperative day. The patient may be moved to a chair and should use a bed bike, exercise bicycle or treadmill as soon as possible. Within a few days of LVAD implant, the patient should be ambulating in the halls and performing mild exercise under the supervision of a physical therapist. The nursing, physical therapy, and occupational therapy staff will work together to prepare the patient for hospital discharge - whether to home or a rehabilitation facility. If discharged to home, at the clinician's discretion, the patient may attend a structured outpatient cardiac rehabilitation program.

18.10 Patient Education

Patient training is critical to ensure safe and successful outcomes. The patient must be able to demonstrate proficiency in operating the HeartWare® System and in responding to emergencies. In order to ensure their understanding and ability, patients should be trained using hands-on demonstrations. At the end of the training, the patient should be able to do the following:

- Identify the AC adapter and successfully connect it to the controller and an electrical outlet.
- Identify the power ports on the controller and be able to successfully replace batteries as indicated.
- Successfully recharge batteries with the battery charger.
- Monitor the remaining battery time on each battery according to LED light displays.
- Identify audible and text alarm messages on the controller.
- Understand the meaning of alarms and demonstrate appropriate responses to alarm conditions.
- Successfully switch from one controller to another controller.
- Understand the importance of not pulling, twisting or kinking the driveline or power cables.

Following hospital discharge, the patient's understanding of HeartWare® System operation and alarms should be re-evaluated during routine follow-up visits. This training should include reinforcement of the procedure for switching to a backup controller in the case of an emergency.

18.11 External Accessories

18.11.1 Patient Pack

The patient pack is used to safely secure, store and carry the controller and batteries. It can be used in or out of the hospital, when resting, sleeping or ambulating. One controller and two batteries fit into the patient pack.

18.11.2 HeartWare® Shower Bag

A shower bag is available for use in conjunction with the HeartWare® System. To ensure safe and appropriate use of the shower bag, all patients and caregivers should be trained on shower bag operation prior to use.

WARNING! DO NOT allow patients to shower until they have received permission from their clinician to do so. Patients who shower must use the HeartWare® Shower Bag.

WARNING! DO NOT allow hearing impaired patients to shower unless their caregiver is close by to hear alarms.

WARNING! DO NOT plug the controller into an AC wall outlet during showers; to eliminate the possibility of a severe electrical shock, it should be connected to two batteries.

WARNING! DO NOT allow patients to take a bath or swim, as this may damage HeartWare® System components and/or result in driveline exit site infection.

WARNING! DO NOT submerge HeartWare® System components in water or other fluid as this may damage them. If this happens, contact HeartWare.

WARNING! DO NOT allow water or other fluids to enter the controller, power adapters, batteries, battery charger or connectors, as this may damage HeartWare® System components. If this happens, contact HeartWare.

CAUTION: DO NOT pull, kink or twist the driveline or the power cables, as these may damage the driveline. Special care should be taken not to twist the driveline while sitting, getting out of bed, adjusting controller or power sources, or when using the shower bag.

18.12 Recommended Equipment for Use at Home

The minimum recommended amount of HeartWare-supplied equipment needed for use at home after discharge from the hospital is:

2 Controllers with AC adapters	1 Patient Pack
1 Battery charger	1 Driveline cover
4 Batteries	2 Alarm adapters
1 DC adapter	1 Shower bag

Whenever patients with the HVAD® Pump leave the hospital or leave their house on an excursion, in addition to what they are currently using, they should bring the following equipment as a backup:

2 Controllers	1 AC adapter
4 Charged batteries	1 Alarm adapter
1 Patient Pack	1 Driveline cover
1 Shower bag	Emergency contact information

WARNING! AVOID areas with high magnetic forces such as theft detection devices or airport security systems, as this may affect HeartWare® System operation.

WARNING! Keep mobile phones at least 20 inches (50 centimeters) away from the controller, as mobile phones may interfere with controller operation.

WARNING! DO NOT let the patient have a magnetic resonance imaging (MRI) procedure while implanted with the HVAD® Pump. Doing so could cause harm to the patient or could cause the pump to stop.

WARNING! DO NOT apply high power electrical treatment (e.g. application of diathermy) directly to the patient, as this may affect HeartWare® System operation.

WARNING! AVOID therapeutic levels of ultrasound energy, as the device may inadvertently concentrate the ultrasound field and cause harm.

WARNING! AVOID therapeutic ionizing radiation since it may damage the device. This damage may not be immediately detectable.

19.0 EQUIPMENT INSPECTION, CLEANING AND MAINTENANCE

19.1 General Care

The HeartWare® System is made of durable materials that will occasionally need cleaning. The following steps should be used to clean the equipment:

1. Use a clean, soft cloth when cleaning the system.
2. Gently clean the equipment. Avoid hard rubbing.

WARNING! DO NOT use any components other than those supplied by HeartWare with the HeartWare® System, as this may affect HeartWare® System operation.

WARNING! DO NOT disconnect the driveline or power sources from the controller while cleaning it or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.

WARNING! DO NOT drop the controller or other equipment. Dropping the controller could cause sudden stoppage of the pump. Dropped equipment should be reported to HeartWare and inspected.

WARNING! Damaged equipment should be reported to HeartWare and inspected.

CAUTION: ALWAYS keep all connectors free of liquid, dust and dirt, or the HeartWare® System may not function as intended.

CAUTION: DO NOT attempt to repair or service any components of the HeartWare® System. If HeartWare® System equipment malfunctions, contact HeartWare.

19.2 Controller

Once a week: Instruct the patient to inspect the controller power connections and connector pins for dirt. This inspection can be done while the patient is changing batteries or when changing from

batteries to the AC adapter. Check the power connections on the controller one at a time. **DO NOT** disconnect both power sources to examine the connections. **DO NOT** disconnect the pump to examine the percutaneous lead/controller connection. This connector should be inspected only during a controller exchange. The patient should not attempt to clean the controller connectors, but should be instructed to contact their VAD coordinator if they notice the connectors are dirty. Exterior surfaces of the controller should be cleaned using a clean cloth. A damp cloth may be used but a wet cloth should not.

19.3 Batteries

Once a week: Inspect batteries for physical damage, including the battery cable and connectors for damage. **DO NOT** use batteries that appear damaged. Damaged batteries must be replaced.

Periodically or as needed:

- If the battery lasts for less than 2 hours after being fully charged, it should be replaced.
- Exterior surfaces of the batteries should be cleaned using a clean cloth. A damp cloth may be used but a wet cloth should not.

CAUTION: **DO NOT** place batteries in water or liquid.

19.4 Battery Charger

Once a week:

- Inspect the battery charger for signs of physical damage, such as dents, chips, or cracks. **DO NOT** use the charger if it shows signs of damage. Contact HeartWare for a replacement.
- Inspect the power cord used to connect the charger to an electrical outlet. Make sure the cord is not kinked, split, cut, cracked, or frayed. Do not use the cord if it shows signs of damage. Contact HeartWare for a replacement.

Periodically or as needed: Unplug the charger from the wall electrical outlet and clean the exterior surface of the charger using a clean, dry cloth. To clean the battery charger, remove the batteries and unplug the charger from the electrical outlet. **DO NOT** place the charger in water or liquid.

WARNING! NEVER clean the battery charger with the power on, as this may lead to an electrical shock.

19.5 HeartWare® Monitor

Once a month: If not in use, check to be sure the monitor is plugged into an AC outlet. This will keep the internal monitor battery charged. If the monitor battery fails to hold a charge, or lasts less than one hour, please contact HeartWare for a replacement. Also, check the monitor AC adapter and power cord for wear or damage and confirm they are working correctly. Turn off the monitor prior to cleaning. Clean the monitor screen with a soft, lint-free cloth. A damp cloth may be used but a wet cloth should not. Use care to avoid scratching or damaging the screen.

WARNING! NEVER clean the monitor with the power on, as this may lead to an electrical shock. **DO NOT** use alcohol or detergent on the monitor display. Gently wipe the display with a soft, lint free cloth.

19.6 Expected Useful Life of HeartWare Components

The HeartWare® System components were designed and tested to function without failing for the following periods:

- HVAD® Pump at least two years.
- The controller is expected to function for at least one-year.
- The battery charger is expected to function for at least one-year.
- The battery is expected to function through a minimum of 500 charge and discharge cycles; this will provide patient support for at least one-year.

19.7 Product Disposal

Specific product disposal considerations for certain HeartWare-supplied equipment appears below. Otherwise, dispose of all expired or damaged equipment according to applicable local, state, and federal laws and regulations. For additional product disposal support and information, contact HeartWare.

Batteries

HeartWare Li-Ion battery cells DO NOT contain lead. Dispose of/recycle HeartWare batteries in compliance with all applicable local, state, and federal laws and regulations. DO NOT incinerate.

HeartWare Monitor

The HeartWare® Monitor contains a lithium battery (replaceable). Dispose of/recycle the monitor's internal battery in compliance with all applicable local, state, and federal laws and regulations. DO NOT incinerate discarded monitor batteries.




Medical Waste Disposal



The explanted HVAD® Pump and associated implantable components must be disposed of in compliance with all applicable local, state, and federal laws and regulations concerning medical waste.

20.0 Device Tracking and Reporting Requirements

The HVAD® Pump is considered a life-sustaining medical device and must be tracked per US Food and Drug Administration (FDA) and other foreign regulatory agency regulations. Compliance is mandatory. Accordingly, all device tracking paperwork must be completed and promptly returned to HeartWare. In addition, any device malfunctions must be reported to HeartWare by the implanting center.

APPENDIX A: QUICK REFERENCE GUIDE FOR ALARMS

Alarm Symbol	Alarm Tone	LCD Display (line 1)	LCD Display (line2)	Potential Causes	Potential Action
Alarm Type: High (Critical)					
None 	<ul style="list-style-type: none">Continuous loudUnable to mute	<no message>	<no message>	<ul style="list-style-type: none">No power to pumpPump has stopped	<ul style="list-style-type: none">Connect two new power sourcesReplace controllerContact HeartWare Clinical Support
Flashing Red 	<ul style="list-style-type: none">Loud, Two-toned alarm - unable to mute	VAD Stopped	Connect Driveline	<ul style="list-style-type: none">Driveline disconnectedDriveline fractureConnector malfunction/ breakageVAD electrical failure	<ul style="list-style-type: none">Reconnect drivelineContact HeartWare Clinical SupportDownload/email patient log files
		VAD Stopped	Change Controller	<ul style="list-style-type: none">Controller failureVAD failureThrombus or other materials (e.g. tissue fragments) in the device	<ul style="list-style-type: none">Exchange controllerContact HeartWare Clinical SupportDownload/email patient log files
		Controller Failed	Change Controller	<ul style="list-style-type: none">Controller component failed	<ul style="list-style-type: none">Exchange controllerContact HeartWare Clinical Support
		Critical Battery 1	Replace Battery 1	<ul style="list-style-type: none">Limited battery 1 or battery 2 time remainingBattery malfunction	<ul style="list-style-type: none">Replace critical battery with fully charged battery or AC or DC adapterChange controller - if new power sources do not correct alarm
		Critical Battery 2	Replace Battery 2		
Alarm Type: Medium					
Flashing Yellow 	Intermittent beep <ul style="list-style-type: none">Gradual increase in alarm volume over time if not mutedAble to mute alarm for 5 minutes or 1 hourElectrical Fault (audio) and Controller Fault (audio) can be permanently disabledPress the scroll button on the controller to clear resolved medium alarm messages	Controller Fault	Call	<ul style="list-style-type: none">Controller component malfunction but pump still working	<ul style="list-style-type: none">Confirm frequency and duration of alarm, concurrent alarms, and pump flow/speed/powerAssess patient for complaints of shortness of breath, chest pain, palpitations, dizziness, etc.Isolated alarm monitored with download at next visit
		Controller Fault	Call: ALARMS OFF	<ul style="list-style-type: none">Controller component malfunctionSuction Detection disabledLow Flow alarm disabledVAD Connect alarm may be disabledHigh Power alarm may be disabled	<ul style="list-style-type: none">Multiple alarms within 24 hours without other issues should be assessed at non-emergent visitMultiple alarms within 1 hour with other alarms or symptoms, replace controller and assess in emergent visitDownload/email patient log files from original (alarming) controller and new controllerContact HeartWare Clinical Support
		High Watts	Call	<ul style="list-style-type: none">HVAD® Pump Watts have exceeded High Power alarm thresholdAlarm threshold set too close to average powerThrombus or other materials (e.g. tissue fragments) in the deviceHigh RPMHigh flowVAD electrical fault	<ul style="list-style-type: none">Confirm correct settings for High Power alarm and pump speedConsider checking blood coagulation labsAssess patient for hemolysisDownload/email patient logs filesCheck for aortic insufficiency, thrombus, etc.Contact HeartWare Clinical Support

Alarm Type: Medium					
<div>Flashing Yellow</div> <div></div>		Electrical Fault	Call	<ul style="list-style-type: none">Fault in continuity of pump-to-controller electrical connectionsPartial driveline fractureConnector malfunctionController component failureVAD malfunction	<ul style="list-style-type: none">Check driveline cover and ensure driveline connector is engagedInspect driveline for defectsDownload/email patient log filesContact HeartWare Clinical Support
		Low Flow	Call	<ul style="list-style-type: none">Average flow below Low Flow alarm thresholdAlarm threshold set too close to average flowSuctionRPM too high or too lowPoor VAD filling (right ventricular failure, hypovolemia, tamponade, arrhythmias, inflow cannula obstruction, etc.High blood pressureOutflow graft kink	<ul style="list-style-type: none">Confirm VAD parametersIf possible, confirm correct settings for Low Flow alarm limit and viscosityConfirm blood pressure (MAP < 85 mmHg)Evaluate cause of poor left ventricle filling (include attaching patient to monitor to evaluate pump wave form) and consider volume resuscitation if indicatedIf no potential patient cause can be identified, download/email patient log filesConsider ECHOContact HeartWare Clinical Support
		Suction	Call	<ul style="list-style-type: none">RPM too highPoor VAD filling (right ventricular failure, hypovolemia, tamponade, arrhythmias, inflow cannula obstruction, etc.)Thrombus or other materials (e.g. tissue fragments) in the device	<ul style="list-style-type: none">Confirm pump flow trends to evaluate a decrease in mean flowDownload/email patient log filesConsider volume resuscitation and/or correct cause of poor left ventricular fillingConsider decreasing pump speedContact HeartWare Clinical SupportConsider ECHO
Alarm Type: Low					
<div>Solid Yellow</div> <div></div>	<div>Intermittent beep</div> <ul style="list-style-type: none">Gradual increase in alarm volume over time if not mutedAble to mute alarm for 5 minutes.	Low Battery 1	Replace Battery 1	<ul style="list-style-type: none">Battery power is low	<ul style="list-style-type: none">Replace low battery
		Low Battery 2	Replace Battery 2		
		Power Disconnect	Reconnect Power 1	<ul style="list-style-type: none">Power source is disconnected or malfunctioning	<ul style="list-style-type: none">Reconnect power sourceReplace power sourceReplace controller
		Power Disconnect	Reconnect Power 2		

APPENDIX B: SYSTEM COMPONENTS

Implantables (*Supplied Sterile - ETO*)

HVAD® pump
10mm gel impregnated polyester graft
Sewing Ring
Strain Relief

Surgical Tools and Accessories (*Supplied Sterile - ETO*)

Tunneler Rod and Handle
Sewing Ring Torque Wrench
Coring Tool
Driveline Extension Cable
Driveline Cap
Hex Driver
Inflow Cap
Driveline Cover

Externals (*Supplied Non-Sterile*)

Controller (includes AC Adapter/Power Cord*, Alarm Adapter*)
Controller DC Adapter
Patient Pack
Shower Bag
Monitor with Display Case (includes AC Adapter/Power Cord*, Data Cable*)
Battery Charger (includes Power Cord)
Battery
USB Flash Drive
Explant Kit

Instructions for Use (IFU)

* Also available as individual item

APPENDIX C: PRODUCT SPECIFICATIONS**Pump**

Mass (or weight)	160g
Volume	50cc
Materials	Titanium, Titanium Nitride & PEEK®

Outflow Graft

	Gel impregnated polyester graft
Length	60cm
Diameter (or size)	10mm
Materials	Gelatin sealed polyester

Strain Relief

Material	PEEK®
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Driveline

Length	119cm
Diameter	4.2mm
Materials	PTFE coated MP35N DFT wire in a silicone inner sleeve with a polyurethane outer sleeve along with a polyester sleeve

Sewing Ring

Materials	Titanium, polyester
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Controller

Weight	0.5kg
Dimensions	13.4x10.5x5.1 cm
Material	Plastic (Absylux™)
Display	Main screen, battery Levels 1 & 2
Messages	Status and 3 alarm priorities
Buttons	Alarm Mute, Scroll Arrow

Battery

Type	Li Ion, rechargeable
Weight	0.5 kg
Dimensions	9.9 x 8.9 x 4.5 cm
Indicators	Battery level LED
Ratings	14.8 V, 51.8 Wh

Battery Charger

Capacity	4 batteries
Recharge Time	5 hours, fully depleted
Weight	1.3kg
Dimensions	28.6x 13.4 x 10.2 cm
Power Source	Local mains AC, 110-240 VAC, 50-60 Hz
Electrical Ratings	100-240 V, 50-60 Hz, 75 VA; 17 V, 4 A output

AC Adapter

Weight	0.7 kg
Dimensions	11.8x7.5
Electrical Ratings	100-250 V, 50-60 Hz, 140 VA; 15 V, 4.0 A output

DC Adapter

Weight	0.7 kg
Dimensions	15 x 8.3 x 5.1 cm
Electrical Ratings	11.5-15.6 VDC, 30-70 W Input; 15 V, 2 A output

Monitor

Type	Notebook with touch screen Input
Operating System	QNX
Weight	2.5 kg
Dimensions	29.9 x 23.5 x 4.5 cm
Electrical Ratings	19 V, 3.2 A input

Monitor AC Adapter

Weight	0.7 kg
Dimensions	16.6 x 9.6 x 5.6 cm
Electrical Ratings	100-250 V, 50-60 Hz, 215 VA; 19 V, 4.7 A output

Software Parameters, Ranges & Factory Default Settings

Parameter	Range	Resolution	Factory Default
Pump Speed	1,800 to 4,000 RPM	20 RPM	2,500 RPM
Low Flow Alarm	1.0 to 9.9 L/min	0.1 L/min	1.0 L/min
High Power Alarm Limit	1.0 to 25 Watts	0.5 Watts	16.0 Watts
Suction Detection	OFF, Alarm	N/A	Off
Hematocrit	20-50% HCT	1%	30%
Data Logging	15 Minutes	N/A	15 Minutes

Notes: All dimensions are given as length x width x height.

PEEK is a registered trademark of Victrex plc.

Absylux is a trademark of Westlake Plastics Company

IEC 60601-1 Classifications:

Type of protection against electric shock:

- AC adapter - Class I
- DC adapter – Class II
- Controller – Class II, Internally Powered
- Battery charger – Class I
- Monitor power adapter – Class I

Degree of protection against electric shock:

Type CF Defibrillation-Proof Applied Parts

Degree of protection against the ingress of water:

- IPX7 (controller, battery pack)
- IPX5 (driveline extension cable)
- IPX2 (AC adapter, monitor power adapter, data cable)
- IPX1 (monitor)
- IPX0 (battery charger, DC adapter)

Recommended environmental conditions for general use:

- Temperature range within 10°C to 31°C (50°F to 88°F)
- Relative humidity range within 30% to 75%
- Atmospheric pressure range within 700 to 1060 hPa (20.70 to 31.30 in Hg)

Environmental conditions for transport and storage:

- Temperature range within -40°C to 70°C (-40°F to 158°F) for monitor, data cable, battery charger, driveline extension cable, and power adapters.
- Temperature range within -20°C to 50°C (-4°F to 122°F) for controller, battery (transport only).
- Temperature range within -20°C to 25°C (-4°F to 77°F) for battery (storage only).
- Relative humidity range within 10% to 90%
- Atmospheric pressure range within 500 to 1060 hPa (14.76 to 31.30 in Hg)

The box label details conditions for transport and storage.

The device label details the environmental condition limits under which the device should be operated.

APPENDIX D: EMC MANUAL REQUIREMENTS GUIDANCE DOCUMENT


Electromagnetic Compatibility

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this user manual.

Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The HVAD® Pump is indicated for use in the electromagnetic environments specified below. The customer or the user of the HVAD® Pump should assure it is used in such an environment.		
Emissions Test	Compliance	Guidance
RF Emissions CISPR 11	Group 1	The HVAD® Pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The HVAD® Pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Complies	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	
Radiated emissions Avionics RTCA/DO-160F, Section 21	Category M	The HeartWare System with 2 battery packs or one battery pack and controller AC adapter is compliant with all related FAA safety requirements and will not interfere with aviation electronics, per Section 21, Category M of the RTCA document number RTCA/DO-160F, as specified in "Use of Portable Electronic Devices Aboard Aircraft" AC number 91.21-1B, Section 8A.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The HVAD® Pump is indicated for use in the electromagnetic environments specified below. The customer or the user of the HVAD® Pump should assure it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Guidance
Electrostatic Discharge IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient / Burst IEC 61000-4-4	± 2 kV on Power Supply Lines ± 1 kV on Input/Output Lines	± 2 kV on Power Supply Lines ± 1 kV on Input/Output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV Differential Mode ± 2 kV Common Mode	± 1 kV Differential Mode ± 2 kV Common Mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interrupts & Variations on power Supply Lines IEC 61000-4-11	< 5% U_T (95% dip in U_T for 0.5 cycles) < 40% U_T (60% dip in U_T for 5 cycles) < 70% U_T (30% dip in U_T for 25 cycles)	< 5% U_T (95% dip in U_T for 0.5 cycles) < 40% U_T (60% dip in U_T for 5 cycles) < 70% U_T (30% dip in U_T for 25 cycles)	Mains power quality should be that of a typical commercial or hospital environment. The HVAD® Pump will always have a battery backup power supply connected.
NOTE U_T is the a.c. mains voltage prior to application of the test level			
Power Frequency Magnetic Fields IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity (cont)			
Immunity Test	IEC 60601 Test Level	Compliance Level	Guidance
Conducted RF IEC 61000-4-6	3 Vrms(150 kHz to 80 Mhz outside ISM bands ^a)	3 Vrms 10 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the HVAD® Pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P} \quad (\text{outside ISM bands})$ $d = 1.2\sqrt{P} \quad (\text{within ISM bands})$
Radiated RF IEC 61000-4-3	10 Vrms (150 kHz to 80 Mhz inside ISM bands ^a) 10 Vrms (80 MHz to 2.5 GHz)	10 V/m	$d = 1.2\sqrt{P} \quad (80 \text{ MHz to } 800 \text{ MHz})$ $d = 2.3\sqrt{P} \quad (800 \text{ MHz to } 2.5 \text{ GHz})$ <p>Where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). ^b</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^c should be less than the compliance level in each frequency range. ^d</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 – At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects & people.</p>			

- ^a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
- ^b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
- ^c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HVAD® Pump is used exceeds the applicable RF compliance level above, the HVAD® Pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartWare® pump.
- ^d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the HVAD® Pump

The HVAD® Pump is indicated for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HVAD® Pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HVAD® Pump as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	150kHz to 80MHz outside ISM bands $d = 1.2\sqrt{P}$	150kHz to 80MHz within ISM bands $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.










NOTE 1 – At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.













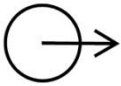

NOTE 2 – The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.









NOTE 3 – An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

APPENDIX E: SYMBOL DEFINITIONS

	Attention, consult accompanying documents
	Follow operating instructions
	Batch code
	Catalog number
	Serial number
IPX0	Keep dry – no water ingress protection
IPX1	Protected against vertically falling water drops
IPX2	Protected against dripping water
IPX5	Protected against water jets
IPX7	Protected against the effects of water
	Defibrillation proof type CF applied part
	Temperature range
	Humidity range
	Atmospheric pressure range

	Date of manufacture
	Manufacturer
	Sterilized with ethylene oxide gas
	Non sterile
	Single use only, do not reuse
	Do not use if damaged
	Properly dispose battery
	Use by YYYY-MM-DD or YYYY-MM
	Direct current power connection
	Monitor connection
	Pump connection
	Input power required
	Output power delivered
	UL Classification Mark. With respect to electric shock, fire and mechanical hazards only in accordance with UL60601-1, IEC60601-1, CAN/CSA C22.2 No. 601.1

	41 CP11/34/SD-2 pin settings		CE Mark
	Diameter		The UL mark, product safety certification
	Latex free		Usable length
	Prescription only symbol		Non-pyrogenic

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